EXHIBIT F

In The Matter Of:
~In Re: Avaulta~

Bobbie Shull, M.D.
02/06/2013

Tiffany Alley Reporting & Video
3348 Peachtree Road
Tower Place 200, Suite 700
Atlanta, GA 30326

770.343.9696
www.tiffanyalley.com

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REPORTING & VIDEO

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C.R. BARD, INC.
PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION: MDL NO. 2187

THIS DOCUMENTS RELATES TO:

LINDA RIZZO and RONALD RIZZO,
Plaintiffs,
vs.
C.R. BARD, INC.,
Defendant.
Case No. 2:10-cv-01224

WANDA QUEEN and GREG QUEEN,
Plaintiffs,
vs.
C.R. BARD, INC.,
Defendant.
Case No. 2:11-cv-00012

VIDEO DEPOSITION OF BOBBIE LEWIS SHULL, M.D.

February 6, 2013 - 9:14 a.m.

Mueller Law Offices

404 W. 7th Street

Austin, Texas 78701

Judith L. Leitz Moran - RPR, CCR-B-2312

CAROLYN JONES,

Plaintiff,

vs.

C.R. BARD, INC.,

Defendant.

Case No. 2:11-cv-00114

DONNA CISSON and DAN CISSON,

Plaintiffs,

vs.

C.R. BARD, INC.,

Defendant.

Case No. 2:11-cv-00195

NANCY SMITH and JOHN SMITH,

Plaintiffs,

vs.

C.R. BARD, INC. and SOFRADIM PRODUCTION SAS,

Defendants.

Case No. 2:11-cv-01355

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APPEARANCES OF COUNSEL:

On behalf of Plaintiffs:

HENRY G. GARRARD III, ESQUIRE
Blasingame, Burch, Garrard & Ashley
440 College Avenue, Suite 320
Athens, Georgia 30601
(706) 354-4000

and

MARGARET M. THOMPSON, M.D., ESQUIRE
Mueller Law
404 W. 7th Street
Austin, Texas 78701
(512) 478-1236

On behalf of Defendant C.R. Bard, Inc.:

RICHARD B. NORTH, JR., ESQUIRE
Nelson Mullins Riley & Scarborough LLP
Atlantic Station
201 17th Street NW
Suite 1700
Atlanta, Georgia 30363
(404) 322-6000

APPEARANCES OF COUNSEL (CONT.):

On behalf of Defendant Sofradim Production SAS:

MICHAEL D. MOELLER, ESQ.
Shook, Hardy & Bacon, LLP
2555 Grand Boulevard
Kansas City, Missouri 64108
(816) 474-6550

Also Present:

Terry Wetz, Legal Video Specialist

(Pursuant to OCGA 15-14-37 (a) and (b) a written disclosure statement was submitted by the court reporter to all counsel present at the deposition and is attached hereto.)

VIDEO TECHNICIAN: And we are on the record. The time is approximately 9:14 a.m.

This is the beginning of Tape 1 of the videotape deposition of Dr. Robert Shull. In Re: Avaulta Pelvic Mesh Support Systems.

Today's date is February 6th, 2013.

My name is Terry Wetz, Legal Video Specialist.

Would counsel present please identify themselves and who they represent for the record.

MR. GARRARD: Henry Garrard on behalf of Plaintiffs.

MS. THOMPSON: Margaret --

MR. NORTH: Richard -- oh, I'm sorry. Go ahead.

MS. THOMPSON: Margaret Thompson on behalf of the Plaintiffs.

MR. NORTH: Richard North on behalf of C.R. Bard.

MR. MOELLER: Mike Moeller on behalf of the Sofradim Defendants.

VIDEO TECHNICIAN: Thank you, counsel.

Would the court reporter please swear

in the witness.

BOBBY LEWIS SHULL, M.D.,
being first duly sworn, was examined as follows:

THE WITNESS: I do.

MR. NORTH: This will be the deposition of Dr. Bob -- how do you pronounce your last name?

THE WITNESS: Shull.

MR. NORTH: -- Shull, taken for purposes of discovery and all other purposes permitted under the federal rules.

Mr. Garrard, as usual, I propose that we reserve all objections except as to the form of the question or the responsiveness of the answer until such time as this deposition is used.

MR. GARRARD: That's fine.

Although, I would state that the court has encouraged us simply to reserve all objections and I will be agreeable to that, but I can also do form and responsiveness, too.

MR. NORTH: Because I often stumble on form, I would be most appreciative if you would make form objections. I'm not willing to

stipulate as to the reservation of all of those.

And what is the witness's preference as to read and sign?

MR. GARRARD: He will read and sign.

MR. NORTH: And we'll stipulate that he may do so before any notary public.

EXAMINATION

BY MR. NORTH:

Q Doctor, would you state your full name for the record.

A Bobby Lewis Shull.

Q And what is your business address?

A I work at Scott & White Clinic in Temple, Texas. The address is 2401 South 31st Street.

Q Dr. Shull, as I introduced myself to you before the deposition, my name is Richard North and I'm an attorney representing C.R. Bard in this litigation where you have been named an expert witness.

Have you ever given a deposition before?

A One time.

Q In what kind of case was that?

A It involved medical care and it's been a number of years ago and I don't remember the details, but it was a question about the adequacy of care for a surgical patient.

Q But some sort of medical malpractice case?

A Yes.

Q And were you testifying on behalf of the physician who was being sued or the patient?

A The physician.

Q Did that involve pelvic floor surgery or do you recall?

A You know, I don't remember the details, but I'm sure it did.

Q Okay. Well, since it's been a while since you've given a deposition, let me ask you to please let me finish my question before you answer it so the court reporter can take it down. And that you please answer out loud and avoid the nod of the head or uh-huh or uh-uh.

And then, also, if at any time you want to take a break today, please feel free to do so. Just let us know and we'll be happy to do so.

And what is your profession, Dr. Shull?

A I practice obstetrics and gynecology, although, for the last 20 years or so my practice has been limited to outpatient gynecology and gynecologic surgery.

Q And just rough calculations, it seemed to me you're probably in your late 60s or early 70s?

A 69.

Q Okay. Are you still practicing medicine full time?

A Yes, I do.

Q Before we get any further, I'd just like to ask you a little bit about your gynecological surgery career.

Have you ever implanted a polypropylene mesh product?

A In the case of suburethral slings for the treatment of urinary incontinence, the answer is yes.

Q Do you still to this date implant polypropylene slings?

A For the treatment of urinary incontinence, yes.

Q How frequently do you perform that sort of surgery today?

A It's variable, but in the course of a year, I would estimate maybe 30 times or...

Q What slings do you presently use? What manufacturer's products do you use in those?

A Primarily, we use Johnson & Johnson's tension-free vaginal tape for retropubic slings. In the occasional case where we do transobturator slings, we'll use the Boston Scientific product.

Q Have you ever used any Bard products for the treatment of stress urinary incontinence?

A To the best of my knowledge, no.

Q So I gather by the way you answered that question, that you have never implanted a transvaginal mesh product for the treatment of pelvic organ prolapse?

A I have not used any mesh products for the treatment of pelvic organ prolapse being placed transvaginally.

Q Have you used mesh for the treatment of pelvic organ prolapse where the mesh was

placed in the body through some other technique or route?

A Occasionally, we'll do abdominal sacral colpopexy. That involves placing a synthetic material transabdominally.

Q How often do you do that procedure?

A We look at our statistics periodically, and in the cases of women who have pelvic organ prolapse, probably 90 or 95 percent of those women are treated with vaginal surgery, about 5 percent are treated abdominally.

I have two associates who are technically more proficient at doing abdominal surgery than I am. Most of the patients who have abdominal surgery are treated by one of my two colleagues.

Q Did you just say that 90 to 95 percent of the patients at your clinic that have this sort of surgery have it through a vaginal route?

A Yes, I did.

Q But you don't perform that surgery?

A The vaginal surgery, yes.

Q You do?

A Yeah, I do.

Q Okay.

MR. GARRARD: Richard, he doesn't mean by that he's putting mesh in there transvaginally. It means he's doing surgery vaginally.

BY MR. NORTH:

Q You're doing -- would you call that native tissue surgery?

A Yes.

Q Okay. So you are estimating that in your -- well, are you part of a practice group at the clinic?

A Yes.

Q And how many gynecological surgeons are in that group?

A In our department of obstetrics and gynecology, we have a variety of locations where we provide care.

In the main campus at Temple, there are approximately 20 people on the faculty, there are 16 residents in training in obstetrics and gynecology, there are three fellows who are doing post residency training in the subspecialty of female pelvic medicine

and reconstructive surgery.

We have other satellites. All together we have about 40 physicians who practice obstetrics and gynecology.

Q At the present time, do any of those surgeons utilize transvaginal mesh products for procedures?

A To the best of my knowledge, no one does.

Q Over the last -- well, let's say since 2005, have any of the surgeons affiliated with your group used transvaginal mesh products?

A For the treatment of prolapse or for the --

Q For the treatment of prolapse.

A For the treatment of prolapse, I'm not aware of that.

Q Did your practice group make a decision at some point that you were not going to use the transvaginal mesh products?

A The group who works with me at Temple has discussed this issue extensively. We have historically treated women with prolapse through a transvaginal native tissue repair.

We have a long history of doing the surgery, recording our outcomes, and reporting on them in the scientific literature.

The introduction of mesh for the treatment of prolapse 10 or 11 years ago was discussed by those of us who worked together, and we have chosen not to use that. We feel that we get nice results with native tissue surgery. We've documented that and recorded it and we're pleased with that.

Q To your knowledge, have you ever used a product manufactured by Bard for the treatment of pelvic organ prolapse or stress urinary incontinence?

A I'm not aware that I have.

Q Are you -- to your knowledge, have you ever used a product manufactured by the French company Sofradim for the treatment of either stress urinary incontinence or pelvic organ prolapse?

A I'm not aware that I have.

Q Same question as to a British company by the name of Tissue Sciences Laboratories?

A I don't know what products they make. Unless they make something for Johnson &

Johnson, for example, I don't believe I would have used it.

Q Over the years, has Johnson & Johnson been your principal product that you've used for the treatment of stress urinary incontinence?

A Yes.

Q Do any of the slings or other mesh products that you've used for the treatment of stress urinary incontinence -- well, are they made of polypropylene to your knowledge?

A The tension-free vaginal tape is made of polypropylene.

Q What about the other products that you use?

A That Boston Scientific has? I can't answer that for sure. I believe it's polypropylene, but I don't know that for a fact.

Q Do either of those products have any porcine or collagen component?

A No.

(Defendant's Exhibit 1 marked.)

BY MR. NORTH:

Q Doctor, let me hand you what's been

marked as Exhibit 1, which was the notice of deposition filed in this case. Do you recognize that?

A Yes, I do.

Q And that requested that you bring a number of documents with you.

What have brought with you today?

A Well, I believe that I have all the patient records. I have the records that were provided me by Mr. Garrard and Dr. Thompson regarding the documents they acquired from Bard and Sofradim. I have some scientific articles which I previously reviewed. I have my report.

I don't know if there's something else I should have. I don't remember anything else. Is there something else I should have?

MR. GARRARD: Richard, let me -- let me add that we have downloaded to a thumb drive all of the materials he has reviewed, medical records inclusive, documents, et cetera, which we're furnishing to you.

MR. NORTH: Are those duplicative of the hard copy materials that are sitting in front of him now?

MS. THOMPSON: Everything that he has

sitting in front of him is on the flash drive, but there are also additional documents on the flash drive that he does not have in front of him.

MR. MOELLER: I just was going to see if I could --

MR. NORTH: Yeah, if Mike can look at that for a while.

MR. GARRARD: You can mark it as an exhibit, whatever you want to do, but...

MS. THOMPSON: So that has all the documents that were listed on his report as --

MR. MOELLER: Thank you, sir.

MS. THOMPSON: -- provided or relied upon.

MR. NORTH: Are there additional documents that he's relied upon that are not listed on his report?

MR. GARRARD: Yeah, he has looked at some updated medical records that are on that flash drive and I've got copies of them here also if --

MR. NORTH: Okay.

MR. GARRARD: -- if you want them.

MR. NORTH: Yeah.

MR. GARRARD: He's also reviewed some depositions, treating doctor depositions and what have you that have been taken in the interim. Some of them may have been taken before, I don't know. There may be something else.

MS. THOMPSON: And that's on the flash drive.

MR. GARRARD: And they're -- they're all on the flash drive. Everything's there.

MR. MOELLER: Can I just ask real quick, Richard. Are these updated records on specific or are they on all of the bellwethers?

MR. GARRARD: I think it's on three of them, Mike.

MR. MOELLER: Okay. I've got --

MR. GARRARD: I think there are updated records on Queen and Smith and --

MS. THOMPSON: Rizzo.

MR. MOELLER: Rizzo?

MR. GARRARD: -- Rizzo.

MR. NORTH: Has the doctor been furnished any additional Bard documents or Sofradim documents for his review besides what was on the list?

MR. GARRARD: You know, I don't want to say, no, he hasn't. If he has, it's not much, but -- but I'm not going to -- I'm not going to say absolutely, no, without looking through the flash drive.

MR. NORTH: So am I correct that we do not have a current list anywhere of the documents he's been provided, we just have them all on this flash drive?

MR. GARRARD: You have them on the flash drive.

MR. NORTH: And there's no listing or index of them on the flash drive?

MR. GARRARD: Is there, Margaret?

MS. THOMPSON: The -- I'm not -- I don't believe that the depositions and the updated medical records were added to the index. But the index is on the flash drive of all the documents he reviewed.

But the additional ones are, as far as I know, the -- the updated medical records and the depositions.

MR. NORTH: If he were furnished additional corporate documents, would those be on the index on that flash drive?

MS. THOMPSON: Yes.

(Defendant's Exhibit 2 marked.)

BY MR. NORTH:

Q Doctor, let me hand you what's been marked as Exhibit 2. Can you identify for the record what Exhibit 2 is?

A Exhibit 2 is Rule 26 Expert Report of -- of Dr. Bob Shull.

Q And that's your report in this case; is that correct?

A Yes, it is. Yes, it is.

Q Now, I notice that on the hard copy stacks of documents that you have in front of you that you brought in response to the notice you have handwritten notes on a number of those; is that correct?

A That's correct.

Q Then I see notes on the top of these binders. Are there notes scattered throughout the binders or just on the top?

A There may be some things underlined as I reviewed the records. I don't have them marked anyplace, but when I reviewed the records, I may have underlined or highlighted something.

What you see on the top is basically an outline of some of the information to help me recall what happened in the event you ask about particular items.

Q And when were those notes prepared?

A They've been prepared over a period of the last few months. I believe the first time I was contacted by Margaret was in May of 2012, and sometime after that I began reviewing some of the records.

Q Had you had any previous contact with Margaret before?

A Professionally do you mean?

Q Well, let's start with professionally.

A Well, Margaret practiced obstetrics and gynecology in Austin and I practiced about an hour away. So in that sense I had contact because sometimes we'd share patients or we go to meetings together or I would see her at professional societies.

Q Okay. Did you -- the way you distinguished between professionally, did you know her personally, too, beyond those professional contacts?

A We didn't have any social interactions.

Q Right.

So these handwritten notes had been prepared over a number of months?

A That's correct.

Q But beyond any underlining or highlighting or something, are all your handwritten notes regarding these documents at the front of each of these?

No. Just answered it.

A There's one right there on Volume III --

Q Okay.

A -- of Mrs. Rizzo. I think the rest are on the front.

Q Okay.

MR. NORTH: At the next break or first break I would like to get copies of his notes --

THE WITNESS: Sure.

MR. NORTH: -- so we could have those and mark those as an exhibit.

MR. MOELLER: Just while we're on short dialogue, we probably should get some

extra copies of these medical reports, too. It can be on a break or if you want me to hand them to you now.

MS. THOMPSON: These two are yours. You want more than that?

MR. MOELLER: Oh, we'd probably want to mark some, too, at some point.

MR. NORTH: Right.

MS. THOMPSON: Okay.

MR. MOELLER: So I figure you'd guys want some --

MS. THOMPSON: Okay. I'll just --

MR. MOELLER: Thank you.

(Defendant's Exhibit 3 marked.)

BY MR. NORTH:

Q Doctor, let me hand you what's been marked as Exhibit 3.

Can you identify Exhibit 3 for the record, Doctor?

A This exhibit is my curriculum vitae.

Q And I would represent to you that this was the version of it that was attached to your report when it was served in October. Has your curriculum vitae been updated since then?

A To the best of my knowledge, nothing

of any consequence has changed since this was done. There have been -- possibly there's one publication that isn't on it, but I don't know that.

Q Doctor, do you know Dr. Donald Ostergard?

A Yes, I do.

Q In what capacity?

A He and I have similar professional interests. We have a similar practice of medicine. We belong to some of the same organizations. We've met at different professional meetings. He and I have not actually worked together in any patient care issues.

Q Have you ever discussed transvaginal mesh products with Dr. Ostergard?

A I have heard him give presentations and I've read some of his publications about mesh products. I've not had a personal discussion with him particularly about it.

Q And you have not had any discussions with him then about your work on this particular litigation?

A No, I haven't.

Q Okay. Is the Scott & White Clinic affiliated with Texas A&M?

A Scott & White Clinic is an organization of physicians and support personnel to provide medical care. The clinic, our hospital, and our health plan are a single organization.

We provide medical education for Texas A&M University College of Medicine. It's done on a contract basis. We're not actually a part of the Texas A&M system or university.

Q And is Texas A&M located in Temple?

A Texas A&M is located in a variety of places. The primary campus is in College Station, but there are campuses all over the state.

Our particular medical school has a campus in Temple, but there are also campuses in other locations.

Q What would be considered the principal campus for the Texas A&M medical school?

A College Station.

Q Okay. Are you presently board certified?

A I'm presently board certified in obstetrics and gynecology.

Q Is there any specific board certification available for gynecological surgery as opposed to just obstetrics and gynecology?

A In the general specialty of obstetrics and gynecology, there currently are three subspecialties for which you can take an examination and be certified by the American Board of Obstetrics and Gynecology. Maternal and fetal medicine, oncology, reproductive endocrinology.

As of June of 2013, there will be an examination for the subspecialty of female pelvic medicine and reconstructive surgery.

There currently is no examination for that specialty so no one is subspecialized or certified in that particular area at the present time.

Q Now, my understanding is you graduated from Duke University?

A I attended Duke University from 1961 to '64. I enrolled in medical school before I graduated.

Q What was your major at Duke?
A German.
Q And so you went straight from Duke to Tulane Medical School?
A Yes, I did.
Q And that was without actually graduating from Duke?
A That's correct.
Q And then you did your internship and residency at the University of Virginia?
A That's correct.
Q And I believe you completed your residency in 1973?
A Yes.
Q And where did you go after that?
A I had been enrolled in a program called the Berry Program which allowed me to be deferred from going into active duty military during my residency program.
I had agreed that when I finished my residency program, I would serve on active duty. At the completion of my residency, I was assigned to Sheppard Air Force Base in Wichita Falls where I worked for two years doing general obstetrics and gynecology.

Q And after your two-year stint at the air force base, what did you do?

A I came to Scott & White and I've worked there ever since.

Q And what year did you begin with Scott & White?

A 1975.

Q In what states are you licensed to practice medicine in?

A Texas.

Q Has your license ever been suspended?

A No.

Q Dr. Shull, do you have any previous training -- or any training at all in biomaterials?

A No.

Q Biocompatibility?

A No.

Q Manufacturing processes?

A No.

Q What about pathology?

A In pathology?

Q Yes.

A As a student, we were required to take pathology. As a resident, we had

pathology as a part of our rotation during our residency program. So if that's what you're asking about, the answer is yes.

Do I practice pathology now? The answer to that is no.

Q So you have not really had any experience with pathology since you completed your residency?

A Not in interpreting the specimen itself. We receive reports from pathology. We integrate that into medical care, but I don't actually do the evaluation of the tissues.

Q You have not ever done any pathology analysis of an explanted mesh material, have you?

A Not microscopically. The extent of my involvement in that has been looking at the gross specimen, not the microscopic.

Q Do you have any experience or expertise in toxicology?

A No.

Q Have you ever worked for a medical device manufacturer?

A No.

Q Have you ever consulted with a

medical device manufacturer in the development of a product?

A I have been asked to sit in groups who are brainstorming about products, including the treatment of urinary incontinence or the pelvic organ -- or pelvic organ prolapse.

So if your question is have I been involved in something along those lines, the answer is yes. Have I actually participated in the development of a product, the answer is no.

Q For what company did you do this brainstorming work?

A Johnson & Johnson.

Q And when was that?

A I can't tell you the specific dates for that. I am presuming it would have been in the neighborhood of 2000, but I don't have a specific time for it.

Q On how many occasions did you do that?

A I can't tell you for sure, but it may have been two times or so.

Q But it's probably been around a decade or so since you did that?

A Well, the TVT was introduced, I

believe, in 1970 -- in 1996. I didn't begin using the tension-free tape probably until about 2001. So I'm thinking these inquiries occurred sometime around 2000 or 2001.

Q Have you ever conducted a clinical study of a new product that was sponsored by a manufacturer?

A No.

Q Have you conducted any or headed up any clinical studies over the course of your career at Scott & White?

A Well, we've reported a number of surgical procedures which we have performed on the preoperative assessment of the patients, on the morbidity associated with the procedure itself, and on the subsequent follow-up of the patient. So the answer to that is yes.

Q What's the largest cohort that you've studied?

A I believe it is 302 patients we reported on who had pelvic organ prolapse treated with a native tissue repair and then followed up and an assessment of the preoperative findings, the intraoperative morbidity. We were particularly interested in

the durability of the operation.

We looked at those patients in several other ways, including how did the preoperative examination compare to the intraoperative examination. How did the participation of residents in the care of the patients affect the outcome.

Q When was that study published?

A 2000, I believe. I can look in my curriculum vitae, but I believe it was 2000.

Q Please do.

A It was published in the American Journal of Obstetrics and Gynecology in 2000.

Q And that was focused on native tissue repair?

A That's correct.

Q Any other clinical studies that you have spearheaded?

A I had previously reported on my experience with treating what are called paravaginal defect repairs. That was, I believe, in 1996.

Q And how large was the cohort of patients for that study?

A I believe there were approximately

200.

I've reported on the evaluation of women who underwent sacrospinous ligament suspension. That was reported in 1992 and there were 81 women in that.

I reported on the use of native tissue iliococcygeus fascia in the treatment of prolapse that was published in 1993. There were approximately 50 patients in that.

Now that I look at my curriculum vitae, the one on paravaginal defect repair was published in 1989.

Q Let me ask you this, Doctor. Have you conducted any clinical studies since 2000?

A We have reported in 2012 on the follow-up of certain women who were treated with native tissue repair for apical prolapse.

We reported in 2008 on the transverse cystocele repair in uterine preservation.

We reported on women who have fail sacral colpopexy and who subsequent were treated surgically.

When I look at my curriculum vitae, that particular reference is given as a presentation, but it in fact has been

published.

Q Obviously, since you've never -- neither you nor your group has ever implanted transvaginal mesh for the treatment of pelvic organ prolapse, you have not performed any clinical studies regarding that procedure or those products, have you?

A We have not done any clinical studies using transvaginal mesh for the treatment of prolapse.

Q Now, you are a member of a large number of professional societies, I gather?

A Yes.

Q Including the American College of Obstetricians and Gynecologists?

A Yes.

Q Have you ever held a leadership position in that group?

A Yes, I have.

Q And what is that?

A I was chairman of the Texas section of the American College. The American College of Obstetricians and Gynecologists is set up in a way that's similar to our states are set up in the -- in the United States. We have state

representatives. In the case of Texas, we would have a chairman, a vice chairman, a secretary and a treasurer.

At the time I worked in the American College, we then were divided into districts. Our district was 7 including a number of states that are geographically adjacent to us.

As of the last several years, however, Texas has been its own district in the American College.

Q Have you ever held any national leadership positions with the American College?

A No.

Q What about with the American Urogynecologic Society?

A I've been a member of the society. I've served on the board. I have been president of the American Urogynecological Society.

Q You were the president of the society?

A Yes.

Q In what year?

A 1996 through '97.

Q Have you been -- have you remained

active with that society since then?

A Yes.

Q Have you been -- well, let me start over.

The American College that we referenced a moment ago is often called under the acronym ACOG, correct?

A Yes.

Q And the American Urogynecologist Society is often called AUGS, A-U-G-S?

A Yes.

Q And are you aware that both ACOG and AUGS had submitted sort of position statements in the last couple of years regarding the use of transvaginal mesh for the treatment of pelvic organ prolapse?

A Yes.

Q Have you personally been involved at all in the development of those position statements?

A No.

Q There was a practice bulletin issued by ACOG regarding these procedures in about the 2004-2005 time frame that's actually cited in your report. Do you recall what I'm speaking

of?

A There was one in February of 2007 which is cited in the report. And then a revised edition of that in September of 2007.

Q Okay. Did you have any involvement in the development of that practice bulletin?

A No.

Q Over the course of the years, have you had any involvement with either AUGS or ACOG in the development of positions, practice bulletins, or policies with regard to the use of transvaginal mesh for the treatment of pelvic organ prolapse?

A No.

Q What about the same question but with regard to any sling or mesh products for the treatment of stress urinary incontinence?

A No.

Q I see from your curriculum vitae that you've been involved with the credentials committee at Scott & White?

A I have and I'm not presently, but, yes, I have been. I served on our board of trustees for approximately eight years.

Q And what was your -- what were your

duties as a part of the credentials committee?

A The medical faculty is required to submit their credentials to be approved to have hospital privileges. We have a group of individuals then who review all of those credentials. The credentials come to the board of trustees for approval.

In addition, I served as chairman of our department for several years and as director of the division of gynecology. When it was time for each of us individually to submit our request for credentials, I, as the director of division of gynecology would review those requests from individual faculty members.

And then at the time I was chairman of the department would look at them for everyone for all privileges to decide whether or not to approve them.

Q If a gynecological surgeon at Scott & White wants to use a Johnson & Johnson TVT product to perform the surgery for the treatment of stress urinary incontinence, do they need to go through the committee to get credentialed for that procedure?

A They would request permission for

treatment of urinary incontinence, and one of the requests may be mid-urethral slings, there wouldn't be a request for a specific manufacturer's product to be used.

Q If when you were on that committee reviewing requests for credentials such as that, would you ever consult with the manufacturer of a device that was going to be implanted as to that manufacturer's view as to whether the doctor was capable of performing that procedure?

A At the time I served in that capacity in obstetrics and gynecology, the only time that question would be applicable, I believe, would have been in the case of mid-urethral slings.

Q Uh-huh.

A And the answer is, we did not consult a manufacturer about that.

Q Was there any reason why you didn't consult the manufacturer?

A I'm not sure we discussed that.

Q Did you feel it was your role and your committee's role to be the arbiter of whether the doctors were competent to use those

slings?

A In our particular practice, in our group practice, we have all chosen certain things which we feel that we can provide the best care.

Not everyone in our department treats women with pelvic organ prolapse. Not everyone treats urinary incontinence. Not everyone does maternal fetal medicine. Not everyone does oncology.

As a consequence, when people request permission to be credentialed in particular areas, they're normally a very specific. As opposed to requesting privileges for everything, they request privileges for the things in which they are most likely to provide care. Could be general outpatient gynecology, general obstetrics.

But in the case of reconstructive surgery, the treatment of fistulas, for example, not everyone would request that. Reimplantation of ureters in the bladder, not everyone would request that. Mid-urethral slings, not everyone would request that.

So for the people who did request it,

you asked do I think that I should know that they're qualified to do the operation? Yes, I would know whether or not they're qualified to do the operation.

Q And you would consider with regard to those physicians who were seeking credentials to use these slings, that it was your committee's role to make the determination whether they should have those credentials?

A As the division director of gynecology, it was my position to approve it or disapprove it. As department chairman, it was my position to approve what had been approved by someone else who was the director of the division of gynecology, so yes.

Q And you made those determinations always without any consultation with the manufacturer, correct?

A That's correct.

Q Do you own any patents?

A No.

Q Have you ever been sued for malpractice?

A You know, prob -- and I can't tell you the number of years ago there was a suit,

and it could have been 25 or 30 years ago, which never -- there was a complaint.

There was nothing that went to court. There was a patient complaint. We have our own in-house legal counsel. We have our own risk management.

And there was an issue of a woman who brought a complaint about having a hysterectomy. I believe that her complaint was that she felt there was an alternate therapy available for her.

It went through our risk management, our internal legal department, it never went to court. I never appeared in court. I don't believe I was ever deposed about it. That was all handled through our internal risk management system.

Q Is that the only malpractice claim or potential claim against you that you recall in your career?

A To the best of my knowledge.

Q Doctor, you would agree that pelvic organ prolapse is a medical condition that can affect a women's quality of life, correct?

A Pelvic organ prolapse is a complaint

which may affect a women's quality of life. There are some women whom we see for examination who have an abnormal physical exam that would by the strict definition qualify for prolapse, and, in fact, the women have no complaints.

Q But in some cases the symptoms can be fairly severe, correct?

A The symptoms of pelvic organ prolapse vary from individual to individual. Some women have minimal complaints, some women have their quality of life affected to varying degrees including significant effect on their quality of life.

Q In cases where the pelvic organ prolapse has a significance impact on the quality of a women's life, how does it affect the woman?

A When I see someone who has pelvic organ prolapse, the complaints generally fall in several categories. They have some complaint with support, they see or feel something that they know isn't normal for them and they're concerned do they have some serious underlying disorder. Do they have a tumor? Do

they have something that will jeopardize their health? So it could be seeing or feeling something.

It could be function. Could be function of the urethra, the bladder, could be function of the bowel, it could be sexual function.

It could be that it affects her ability to have a good image of themselves. That their body image is adversely affected because they know their pelvic exam is abnormal.

It could be because it affects their ability to do physical activities they enjoy doing, working, exercising. So the spectrum of complaints is variable.

Q And there is a grading system that physicians use to assess the severity of pelvic organ prolapse; is that correct?

A There are several ways to assess prolapse. One is through a history. So you ask someone about their symptoms.

Another is to fill out some quality of life instruments or documents that inquire specifically about bowel function, bladder

function, sexual function.

Another is the physical examination. On physical examination, until approximately the mid-1990s, there was no recognized objective system for quantifying the amount of prolapse that someone has. Up until the mid-1990s, people use very nondescript terms to describe these physical findings.

I happen to be a member of a committee which published the report on pelvic organ prolapse quantification system in 1996 that was soon adopted by most organizations around the world as being an objective way to quantify the amount of the prolapse.

So history is one way to document someone's concerns, a physical exam can be objectively described, and then there are certain tests of function, bowel function, bladder function. There are no reproducible, quantifiable tests for other complaints.

Q What about the POP-Q test?

A The POP-Q test is a pelvic organ quantification system. And as I indicated earlier, I was a part of the committee which published that.

And since my name begins with S, it always comes under the et al. in the publication. But if you look in 1996 in my curriculum vitae it is No. 17, The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction.

Q What is the Baden-Walker method?

A The Baden-Walker method is a way to describe pelvic organ prolapse which was originated by Dr. Wayne Baden and Dr. Walker, both of whom worked in the department where I work in Temple.

And the Baden-Walker system is a slightly different way to describe the extent of prolapse. I believe Wayne published about that in the 1970s.

It frankly is a method I prefer because it's more simple. It's easy to describe. And even though I helped with the description of the POP-Q, the truth is I prefer the Baden-Walker system for the general nurse or doctor who is going to see a patient because it's very understandable.

Q And so is the Baden-Walker system what you use generally in your practice?

A Yes, it is.

Q What age range of women does pelvic organ prolapse affect?

A Pelvic organ prolapse normally is a function of age. If you look at all women who have prolapse, there are a miniscule number of females who have a congenital predisposition to prolapse.

So a tiny number of women are born with certain congenital abnormalities that we know will result in pelvic organ prolapse. Exstrophy of the bladder is one of those.

So prolapse may occur at a relatively young age. Young girls with meningomyelocele may have a congenital predisposition to prolapse.

When you exclude those, the vast majority of women then who have pelvic organ prolapse have previously had a delivery, a pregnancy and a delivery. Usually the delivery has occurred vaginally.

So in my practice I will occasionally see someone who with their first delivery at a young age has terrible pelvic floor damage. A women in her 20s. That's the exception.

The majority of women have completed child bearing and are in their 40s, 50s, 60s, 70s or 80s by the time they present for evaluation and care.

Q Would you agree that it is therefore infrequent that you see a patient presenting with prolapse who is in her 30s?

A If you look at all the patients that we see for prolapse, the women in their 30s are a smaller percentage of our patient population than women who are in their 50s, 60s, 70s and 80s.

Q What is your recollection of when transvaginal mesh products for the treatment of pelvic organ prolapse first went into general use in your profession?

MR. GARRARD: Wait a minute. Would you just repeat that question, please.

MR. NORTH: Let me rephrase it.

BY MR. NORTH:

Q Doctor, what is your recollection as to when products, transvaginal mesh products, for the treatment of pelvic organ prolapse were first introduced in the market and used widely by physicians?

MR. GARRARD: Object to the form in terms of your terminology used widely.

A Whenever I look at the history of using something to supplement native tissue repair in vaginal reconstructive surgery, there are several stages.

Sometimes women can be treated by using their own body's tissues. That's called autologous tissue because it comes from a person who is using it.

So there's been a history of using autologous tissue for certain things in reconstructive surgery that goes back decades.

When you look at the use of a xenograft or an animal product, some people were using xenografts probably 20 or 25 years ago. Used as a -- basically an applique, a standard repair was done, something then was used to reinforce whatever you had done using suture materials and perhaps the patient's own tissue or perhaps even a xenograft.

The next phase of that and this particular instance of using a synthetic material such as polypropylene, individual physicians probably have used that off and on,

I would estimate, for 20 or 30 years.

A report about it in 1996 from Tom Julian, who is from the University of Wisconsin, has been cited by a number of authors because Tom treated about 25 women by placing polypropylene and suturing it into place. The change in the concept of using products then happened sometime after 1996.

In 2000 or 2001, Peter Sand presented a report at an organization that he and I both belonged to, the Central Association of Obstetricians and Gynecologists, on using polyglactin an absorbable mesh for cystocele.

And when you look at his article, actually, I happen to be one of the reviewers in the comments on his presentation.

After the 2000 -- late 1990s, 2000 interval, there was more interest in trying to use products.

The current system of using trocar-based application of products is a departure from the use of a specific applique sutured in place.

The trocar-based products were, I believe, first cleared by the FDA in 2002. So

they've had a relatively short history.

The other interest in doing something to reinforce vaginal repair to surgery has gone on for a longer time period.

BY MR. NORTH:

Q Did you ever use xenografts in your practice?

A I have not used a xenograft. I've used autologous material, patient's own fascia.

Q And I may have asked it this way earlier but I may have limited it, too. I just want to be sure I'm clear.

Have you used any mesh ever for the treatment of pelvic organ prolapse?

A Through the vagina?

Q Through the vagina.

A No.

Q Okay. Do you know whose product, trocar-based product, was first cleared by the FDA in 2002?

A For the treatment of prolapse, let me look at that and see.

Actually, I don't know whose -- I don't know whose it was actually. I don't know if it was AMS or J&J. I can't answer that.

Q Well, you would agree that Bard is not the first company to introduce a trocar-based transvaginal mesh product to the market, would you?

A For the treatment of pelvic organ prolapse?

Q Yes.

A To the best of my knowledge, Bard was not the first company to do that.

Q Are you familiar with the manufacturing processes for polypropylene mesh?

A No.

Q Do you know how the product is sterilized?

A No, I don't.

(Defendant's Exhibit 4 marked.)

BY MR. NORTH:

Q Let me show you what's been marked as Exhibit 4.

MR. GARRARD: Thank you, sir.

BY MR. NORTH:

Q Dr. Shull, Exhibit 4 is actually what was Exhibit B to your expert report in this litigation, correct?

A I don't know the answer to that.

These are references I used, but you asked me if it's Exhibit B and I don't know the answer to that. I'll have to look and see where Exhibit B is.

Q Well, let's look back at your report then.

A I see, it's on Page 2. A list of these materials contain Exhibit B.

Q Right.

A I want to look that up. I don't see it in that form, so, I don't know how to answer that question.

THE WITNESS: Do you?

BY MR. NORTH:

Q I'm sorry, what's that?

A I don't see -- in these documents I don't see something that is itemized the exact way you have it. And you asked me if that's Exhibit B and I can't answer that for sure because I don't --

MR. GARRARD: Richard, to save you some time, I will agree that Exhibit B was attached to his report.

BY MR. NORTH:

Q Well, with that stipulation by your

-- or agreement by Mr. Garrard, Exhibit B that was attached to your report was supposed to be a list of all the materials you reviewed.

A Yes.

Q And you have no reason to dispute Mr. Garrard's representation that this is in fact that list of materials, do you?

A I do not.

Q Now, these materials contained a large number of documents that came either from Bard itself or in a few instances from Sofradim; is that correct?

A Yes.

Q And did you pick out the documents you were going to review in that regard or were those furnished to you by the Plaintiff's counsel?

A I was given a set of documents which I reviewed and highlighted the ones I thought raised questions or concerns in my mind.

Q But my question is, who chose the documents that were sent to you? They selected which documents would be sent to you originally, correct?

A Are you asking did I request

documents from Bard or Sofradim?

Q No.

A I did not request them.

Q That's not my question, Doctor.

My question is, did the Plaintiff's attorneys determine or select which documents from Bard and Sofradim would be sent to you?

A They provided me the documents.

Q Well, and they selected which documents to send to you, correct?

A I'm presuming they chose them.

Q I mean, they didn't give you -- well, are you aware of the fact that approximately 11.5 million pages of documents have been produced in the litigation so far?

A I didn't know that.

Q Well, they did not give you an index of all the documents that were produced in the litigation and ask you to identify from that index which ones you wanted, right?

A That's accurate.

Q Instead, they chose which ones you would -- they would send to you and sent them to you as a package?

A That's correct.

Q And you would agree that you weren't sent 11.5 million pages, I would assume?

A I don't believe. If they were sent, they were never received.

Q Once you reviewed the documents they sent you, did you make a request to see any other documents from the company?

A No.

Q If we could look at Exhibit 3. And the pages aren't numbered, but let's see. Let's just go through it sort of page by page.

On the first page are documents with a Bates number SMITHN, and I'm assuming those are --

A Did you say Exhibit 3?

MR. GARRARD: 4.

A Exhibit 4.

BY MR. NORTH:

Q I'm sorry, Exhibit 4, which is also Exhibit B.

These appear to be medical records from certain Plaintiffs in the action, including Nancy Smith, Cisson, Queen, and Rizzo.

A That's correct.

Q And then once you finished the listing of the Rizzo documents, there are a number of medical articles listed; is that correct?

A Yes.

Q And in fact, there are a number of -- number of medical articles sort of scattered through this listing as you go through it page by page, correct?

A Yes.

Q And those medical articles were selected and sent to you by the Plaintiffs' attorneys; is that correct?

A No. Some of these I requested myself. Some I was familiar with already.

Some I knew the general idea of the content, but I didn't have the specific publication in my hand.

An example of that would be the American College Bulletin from 19 -- from 2007. And then the subsequent revision of that document later in 2007.

Q Well, let me ask you this, Doctor. Did you request specifically all of these medical articles or were there a subset of the

medical articles that the Plaintiffs sent to you saying you need to have this as a part of your file?

A I was provided part of the articles without my requesting them.

Q Okay. Can you estimate what percentage of the articles you were provided without a specific request?

A Perhaps 50 percent.

Q Doctor, did you participate at all in the FDA's hearings in September of 2011 --

A No.

Q -- with regard to mesh products?

A No, I did not.

Q Have you ever consulted with the FDA in any capacity?

A No, I have not.

Q So you've never served on an FDA advisory committee of any sort, have you?

A No.

Q Have you ever prepared a 510(k) submission to the FDA for the approval of a medical device -- or clearance of a medical device?

A I have not.

Q Have you ever prepared a premarket application or amendment, a PMA, to the FDA for the approval of a medical device?

A No.

Q Have you ever drafted any warnings with regard to a medical device?

A No.

Q Have you ever drafted or prepared any instructions for use for a medical device?

A No.

Q Have you ever read an instructions for use for a medical device?

A Yes.

Q With how many devices would you estimate over the years?

A I have read the instructions for use for the devices that I use, the suburethral slings.

I have reviewed the instructions for use on some of the transvaginally-placed mesh products, even though I've not used the products. In some cases I have looked at the DVDs provided by the manufacturers. In addition to have reading -- having read the product information forms.

Q Well, your review of instructions for use with regard to transvaginal mesh products for the treatment of pelvic organ prolapse has all been in the context of your work in this litigation, hasn't it?

MR. GARRARD: Object to the form --

A No.

MR. GARRARD: -- of your question. That's not accurate.

BY MR. NORTH:

Q Have you looked at those instructions for use of products for the treatment of -- transvaginal mesh products for the treatment of pelvic organ prolapse in some other context?

A From another manufacturer or in another context?

Q Either one.

A Well, I have looked at other manufacturer's instructions for use before I was ever knowledgeable about the case against Bard.

Q Are you familiar with the fact that there's similar litigation pending against Johnson & Johnson?

A Yes.

Q And that there's similar litigation pending against Boston Scientific?

A Actually, I didn't know that, but it doesn't surprise me, but I didn't know that.

Q Do you use catheters in your practice, urinary catheters?

A Yes, we do.

Q What brand do you use for catheters generally?

A I believe it's Bard, but I can't tell you that for a fact.

Q So you have used, to your knowledge, some Bard devices over the years, correct?

A Yes.

Q And to your knowledge, are you still using Bard devices?

A Yes.

Q Do you know whether you've used over the years any devices manufactured by Covidien?

A When you say devices, could you be more specific about that and maybe I could answer that accurately.

Q I'm going to let my colleague be more specific about that. Do you recall just generally right now?

A I don't know who produces some of the things we use at work, frankly. So it's quite possible because I believe our organization maybe has a contract with Covidien for certain items, but I don't know what they are.

Q Are you familiar with the federal regulations promulgated by the FDA concerning the content of instructions for use with regard to medical devices?

A I don't think I understand the question.

Q Are you familiar with the federal regulations that govern what goes into -- what types of information goes into instructions for use with regard to medical devices?

A No, I'm not.

Q Have you ever developed a training program for the use of medical devices?

A In our department we have taught courses on surgery. We began probably in the 19 -- early 1980s doing a postgraduate course on the evaluation and management of women with pelvic organ prolapse that was entirely didactic. There were no hands-on experiences of any kind.

For approximately the last 15 years once or twice a year we teach a course that is didactic classroom enhanced by videos.

And at the end of a one-and-a-half-day session, normally I would be the one doing live surgery, the registrants then sit in a classroom and watch me perform the surgery that we have been discussing for the previous day and a half.

We modified that about maybe seven or six years ago to include a session with cadaver demonstration of the anatomy we're discussing.

In the case of mid-urethral slings, we have used the cadavers to demonstrate the placement of a trocar for a mid-urethral sling.

In the case of dissection for other types of prolapse, we have not used products to demonstrate with the exception of mid-urethral slings.

Q Well, these training programs that you've just described, those are all, as I understand it, developed by the doctors at your clinic?

A That's correct.

Q You have not worked with a

manufacturer of a medical device to develop a training program for that specific manufacturer's devices, have you?

A I have not.

Q Have you ever attended a training program sponsored by a device manufacturer?

A Before I began using the tension-free vaginal tape, it had been on the market for about five years. Actually, I knew a lot about them from reading and conversation with people who are users of the product.

Before I used the product myself, I had seen other surgeons around the world use the product.

Specifically to your question, however, I went to Pennsylvania to spend a day with Vince Lucente for him to demonstrate in his own patients the placement of a tension-free vaginal tape before I returned and used the product myself.

Q And was your trip to see Dr. Lucente sponsored by Johnson & Johnson?

A Yes, it was.

Q Other than that one day spent with Dr. Lucente, have you ever attended a training

program sponsored by a device manufacturer for the use of a specific device?

A You know, I don't think I have. I've gone to other anatomy programs and sometimes people will be demonstrating a product. But I don't believe I've gone to one to be educated about the use of someone's product.

Q Okay. And you've never attended a cadaver lab, for example, for -- sponsored by a manufacturer for training on one of these devices, have you?

A I don't believe I have. I've taught at courses where cadavers are used.

Q And this one day you spent with Dr. Lucente being trained or shown a procedure with the Johnson & Johnson TVT, that would have been about a decade ago roughly?

A Approximately. About 2001 or 2002, someplace in there. I have it in my records some place.

Q And you know Dr. Lucente?

A I do.

Q Have you kept in touch with him over the years?

A I see him at many professional

organizations. I actually gave his oral board exam when he was certified by the American Board of Obstetrics and Gynecology.

MS. THOMPSON: And you passed him?

THE WITNESS: I did.

BY MR. NORTH:

Q You've told us that you've never implanted a transvaginal mesh product for the treatment of pelvic organ prolapse, and to the best of your knowledge, neither has anybody in your group, correct?

A That's accurate.

Q Have you ever witnessed another surgeon implanting a transvaginal mesh product for the treatment of pelvic organ prolapse?

A I have. I operate around the world with some frequency. I've gone to Italy a number of times to operate, to other countries, to India, to Central America.

But in the case of going to Italy, for example, there normally would be five surgeons who are there invited to operate, five or more. And we may watch other people operate and they may watch us do our surgery.

I happened to be there a few years

ago when Dr. Jacquetin was working on one of the mesh products that he's helped developed. So I saw him early in the development of the transvaginal mesh for the treatment of prolapse employ that technique.

I was in the op -- I didn't scrub with him, but I was in the operating room and watched him actually do the procedure. And after these sessions where multiple surgeons come, then we normally will discuss what people's various interests and skills are.

Q Could you spell his name for me?

A J-A-C-Q-U-E-T-I-N.

Q Is he from Italy?

A France. Bernard Jacquetin.

Q Do you know what product he was implanting?

A At the time I didn't. And actually, I still don't know that today. I know he was doing a synthetic product, but I did not know the manufacturer or the name of the product.

Q Is that the only time that you have seen an implant procedure or witnessed one or observed one with a transvaginal mesh product for the treatment of pelvic organ prolapse?

A No. I've seen it on many occasions. I've gone to India five times to volunteer to operate. Usually there are surgeons from around the world who come to the same hospital. People use various techniques.

I normally go specifically to teach using native tissue surgical procedures for a variety of reasons. One of them, I'm comfortable with it. Another is in a developing world it's helpful to know how to use things and have very little cost associated with them.

When I am there, other surgeons will be using various products.

Q To your knowledge, have you ever seen another surgeon implant an Avaulta Biosynthetic, Avaulta Plus or a Avaulta Solo mesh product?

A No.

Q As a part of your practice, do you treat some patients who have -- come to you with complications from mesh implanted by other surgeons?

A Yes.

Q Have you ever performed any surgeries

to remove mesh from a patient?

A Yes.

Q On how many occasions would you estimate?

A I can't tell you the total number, but over the past five to six years the percentage of our surgical practice that has evolved into the management of various complications of mesh is probably 15 to 20 percent of our total number of surgeries.

The three of us together do approximately 400 operations a year.

Q 400 mesh removal operations?

A We do 400 total surgeries per year and probably 10 to 20 percent are related to some complication of mesh.

Q To your knowledge, have you ever removed an Avaulta Biosynthetic, Avaulta Plus or Avaulta Solo mesh product?

A Yes.

Q On how many occasions do you believe?

A I can't answer that. I don't know the answer to that.

Q Do you think it's more than 10?

A I don't think it is.

Q How -- on those occasions, how did you know that it was an Avaulta product?

A When we see patients in referral -- my practice is primarily a referral practice -- we may receive the physician's records when the patient presents for the first visit. We may request the records and be sent them later. Sometimes we never receive the records.

The way to know specifically if a particular product has been used generally is because the operative note would state it.

However, there are some surgeons who use products for surgery but do not include the trade name of the product in the operative report. They'll simply indicate they used a mesh product and you could not identify the trade name from the operative note.

Q Well, with the mesh removal surgeries that you've performed over the last five years that -- and your group has performed, have the number of surgeries that -- where you could determine that it was an Avaulta product been a small percentage of those mesh removal surgeries?

MR. GARRARD: Doctor, if you know,

answer the question, but I ask you not to guess or speculate.

A See, I don't know the answer to that because there are three of us together and I can't answer that question specifically.

BY MR. NORTH:

Q What about with you personally?

A I know that I've removed Avaulta. I have not kept a list of the different products to be able to answer that question for you with any degree of accuracy.

Q Well, you have also performed mesh removal surgeries with Johnson & Johnson products, correct?

A I've removed mesh made by different manufacturers, that's accurate.

Q And you've removed mesh manufactured by Boston Scientific?

A I probably have. The truth is I don't know the trade names and the connection to the manufacturer for everything.

Q But -- okay. Well, let me ask it this way. You have removed a number of meshes over the years that were not Avaulta mesh, correct?

A Not all the meshes we've removed have been Avaulta.

Q Right.

A That's certainly true.

MR. GARRARD: When you get to a reasonable stopping point, I --

MR. NORTH: Yeah, I think it's a good point now.

VIDEO TECHNICIAN: Stand by, please.

We are off the record. The time is 10:33. This is the end of Tape 1.

(Recess taken.)

VIDEO TECHNICIAN: And we are back on the record. The time is approximately 10:48. This is the beginning of Tape 2 of the videotape deposition of Dr. Robert Shull.

You may continue, sir.

BY MR. NORTH:

Q Dr. Shull, do you speak any foreign languages?

A Not fluently. I can speak some Spanish, some German. At one time a little bit of Italian. But I'm not fluent in anything other than English.

Q Any French?

A No.

Q We were talking about your mesh removal surgeries when we -- right before we took the break and what you had witnessed with regard to implant.

While you have not to your knowledge observed an Avaulta implant surgery live, you have seen some DVDs or videos of the implant procedure, correct?

A Yes.

Q And those videos were on a cadaver, weren't they?

A To the best of my knowledge, that's correct.

Q Now, in any mesh removal surgeries you performed over the years that involved an Avaulta product, do recall making an examination of the explant, the Avaulta mesh at the time you did the surgery?

A By gross visualization, we made an observation. We normally record the dimensions. Something about the characteristics of the mesh may be included in the operative note itself.

Q Have you performed any testing on any

Avaulta mesh that you have explanted from that patient?

A Beyond looking at it, recording the dimensions, we would send it to the pathologist. The pathology report usually is very similar to what I just told you, they record the dimensions and there normally is not a microscopic examination.

Q Have you taken over the years pictures of any Avaulta mesh implant or explants that you've removed?

A I don't know the answer to that.

Q Do you recall as you sit here?

A No.

MR. NORTH: Sorry about that.

BY MR. NORTH:

Q As you sit here today, can you recall anything different or unusual about the Avaulta mesh explants you may have seen over the years as compared to other manufacturer's mesh explants you've looked at?

A No.

Q Do you know the name of Johnson & Johnson's transvaginal mesh product for the treatment of pelvic organ prolapse?

A I believe it's Prolift.

Q Have you ever removed any Prolift in a mesh removal surgery before?

A Yes.

Q Can you estimate on how many occasions?

A No.

Q I noticed that a number of your publications involved squirrel monkeys?

A Right.

Q Can you explain to me what the significance of squirrel monkeys are in your practice?

MR. GARRARD: You want to buy one to take home?

A Squirrel monkeys weigh about 800 grams. There are 454 grams in a pound. Squirrel monkeys are little. They have a life expectancy of about 20 or 22 years. They develop prolapse.

There are no good animal models to evaluate prolapse in the mammal family. We learned by serendipity through one of our PhDs who has an animal colony with squirrel monkeys that they develop prolapse.

About 20 years ago, we began to look at these animal colonies. We realized we could do some things with animals that you can't do with humans.

Their life expectancy is shorter. They do develop prolapse. It's possible to create an experimental model trying to learn about factors that predispose to prolapse or interventions that may prevent prolapse.

The reason we were curious about that is because in the history of medicine in general, if you're able to prevent a disease rather than treat the disease, there's a public health benefit to that.

And that's how all of our health has improved over a period of hundreds of years.

A good example of that in OB-GYN, for example, is perhaps when your parents were born, if your mother's mother had been Rh-negative and your mother were Rh-positive, your mother may have sustained intrauterine disease destroying her own blood cells, for example.

That could have occurred in the '40s, '50s, and even in the 1960s. Now that almost

never occurs in a developed country because that disease can be prevented.

In the case of pelvic organ prolapse, our curiosity is can you do something to prevent the development of pelvic organ prolapse; and if so, how can you evaluate it. The animal model provides you an opportunity to do that.

So over the past 20 years we've had a number of publications on this particular animal model describing the anatomy, the gross anatomy, the neurological anatomy.

We followed their obstetrical histories and we've done some interventions, asking the question, if you do certain things, does that predispose the animal to develop prolapse more quickly, for example.

So this specific animal model has been used in an effort to try to learn more about the causes of prolapse and what could we do to prevent it because in this area we're discussing now about the surgical management of prolapse, we're at a point in time where particular strategies are being used, but those strategies are going to go away because

medicine is changing.

In the case of using any materials, for example, what is likely to happen is the whole issue of reinforcing a repair may evolve into we would take some of your blood cells, some of your fat cells, some of your muscle cells, and we may create something that your body recognizes to enhance the surgical management of whatever it is.

If that's the situation, many of these issues about complications associated with whatever we're doing now may not be important.

So we're looking at things about etiology and about interventions. It's unrelated to the surgical strategy of treating prolapse.

When we write about surgical strategies, we're writing about our experience with patients that we see, what we do, are there complications. And if there are, how we manage them, how do we reduce the complications, and how do we increase the durability. In this case the durability of surgery for prolapse.

BY MR. NORTH:

Q Well, that leads me to my next question then. I gather that you have never actually performed surgical tests with squirrel monkeys?

A I haven't personally, our lab has. So, yes, we have PhDs in the lab and physicians in the lab who do that. I have not personally done the surgeries.

Q Have you ever designed any sort of animal test for the implantation of some sort of product or device?

A Our group has. I didn't personally.

Q I'm asking about you personally.

A No, I haven't.

Q You've never developed a protocol for an animal test?

A No.

Q You've never performed an animal test personally?

A No.

Q Have you ever witnessed animal testing taking place?

A How do you mean witnessing? The implantation of a product or the explantation

of a product?

Q Right.

A No.

Q And to the extent that's done in your group, that's done in the laboratory with other physicians and PhDs?

A That's correct.

MR. NORTH: If we could mark this as the next exhibit. Is that No. 5?

THE COURT REPORTER: Uh-huh.

(Defendant's Exhibit 5 marked.)

MR. GARRARD: Do you got one that my old eyes can read?

MR. NORTH: We are all in the same boat, Mr. Garrard.

BY MR. NORTH:

Q Doctor, is this an article that you had prepared in the past?

A Yes.

Q And when was this published?

A December 1994.

Q This did not have to do with the implant of any mesh product, did it?

A In this series of 62 women, we used native tissue and suture material.

Q And in fact, in this particular study, 21 of the 62 patients developed some sort of defect or combination of defects after the surgery; is that correct?

A When we analyze these patients and describe their physical findings as grade, this is using the Baden-Walker system, Grades 1, 2, 3 or 4, certain women had poor support in some segments greater than normal would be Grade 0. So some had more than Grade 0.

Q Look at Table V, if you will, on Page 6 of 12.

A Okay.

Q Does that give a recurrence rate after the native tissue surgery?

MR. GARRARD: Which table, Richard?

MR. MOELLER: Table V.

MR. NORTH: Table V, Page 6 of 12.

MR. GARRARD: I've got Table IV I believe is what you're referring to. Perhaps I'm --

BY MR. NORTH:

Q I'm looking at the very bottom of the page. Is that -- that may not be Table V. It says Table V under it.

A Yeah, I see it. I'm just reading it a minute.

Q Maybe that's Table IV.

A (Witness reviews document.)

Q My question is pretty simple from that, Dr. Shull. Doesn't that indicate that after the native tissue surgery performed -- that was done for these 62 patients that at the first postoperative visit 34 percent of those patients still had support defects of some sort?

A I'm going to answer that just as soon as I read that.

If you read the table you're referring to, it says Groups of Patients and the Number. Patients undergoing vaginal repair performed transvaginally, there were 62. Patients with no defects at 6 weeks, there were 58 patients with no defects at 6 weeks, and that would give a 94 percent. Patients with support defects at any site, and if you look at the asterisk, it says, Patients with loss of support any site at any time after surgery, there were 21.

If we go farther down the

explanation, the support defects, halfway to the hymen, those were 16 of the 21. If we have support defect to the hymen, there were three.

So of the 62 women at any time in the follow-up who had something prolapsing outside the hymen, 2 of the 62 patients had something outside the hymen.

Q Okay. But my question is, 34 percent of the patients following the tissue repair surgery showed some support defect following the surgery, correct?

A At a visit, 21 of these 62 patients had one or more areas that had some degree of pelvic support loss.

Q Okay.

MR. NORTH: Let me have this marked as Exhibit 6.

(Defendant's Exhibit 6 marked.)

BY MR. NORTH:

Q What is No. 6, Dr. Shull?

A Exhibit No. 6 is an article which I published in the American Journal of Obstetrics and Gynecology in 1999 entitled Pelvic organ prolapse: Anterior, superior, and posterior vaginal segment defects.

Q And here you're talking generally about native tissue surgeries to correct pelvic organ prolapse?

A Yes.

Q And at that time you were compare -- you made some comparison to the treatment of pelvic organ prolapse to the treatment of hernias, correct?

A Yes.

Q And what were the similarities there in your mind?

A Pelvic organ prolapse is similar to a hernia in the sense that hernias are related to poor support in connective tissue.

You or I could have a hernia in your diaphragm, your abdomen, your groin.

In the case of women, they could have hernias in the pelvis. They're associated with some abnormality of the normal continuity of connective tissue in the area where the connective tissue should be supporting either a part of your bowel or in the case of women the bladder, the top of the vaginal canal.

Q Now, looking at Page 7 here. In discussing --

MR. GARRARD: Wait a second. Were you adding something?

THE WITNESS: No.

MR. GARRARD: Okay.

BY MR. NORTH:

Q In looking at Page 7 here, you actually are reporting on studies that show that with a native tissue surgery, there's a 29 percent reoperation rate; is that correct?

At the bottom of 6 going over to 7.

A I'm going to find the reference.

I use Reference 7 which is a report by Drs. Olson and associates published in 1997 in Obstetrics and Gynecology. And I use that reoperation rate.

Q And that indicated a 29 percent reoperation rate after native tissue surgery; is that correct?

A That is what it indicated. Subsequently, that article has been reviewed more significantly.

Of these women who were reoperated, several were reoperated for recurrent prolapse. Others were reoperated for the acquisition of other complaints such as urinary incontinence.

So they may have been reoperated, but not for correcting the previous concern, but because of the acquisition of another complaint.

Q Well, regardless of any reinterpretation of that source, it was your view at this time that even the most effective treatments had significant failure rates; is that correct?

A In these author's hands, yes, it did.

There's a difference between a reoperation rate, which they indicated was 29 percent, and someone's returning with a physical exam which isn't perfectly normal.

And the way we've come to know about that -- there are a lot of ways we'd know about it. One of the ways we've come to learn about that is there are now reports in our literature which describe the physical findings of women over the course of decades of life.

So there are groups of women who have been seen at -- in their 30s, 40s, 50s, 60s, 70s and 80s. Someone then has given a profile of what are these examinations, how are they described in women in each of these different

decades.

We know, for example, that women who had children who are in their 50s and 60s do not normally have perfect support in the pelvis. It doesn't mean they're going to be symptomatic or have surgery.

The analogy I would use for that, which I think a patient would understand, is a woman who is 60 or a man who is my age doesn't look the same as an 18-year-old. Their pelvic exam isn't the same as an 18-year-old. So pelvic exams change as people change in age.

What we understand now, for example, I'll use these patients we described with a Grade 1 loss of support. That's something halfway to the hymen.

It would be exceptional now for someone to recommend any intervention for a woman who has physical findings like that.

And in fact, most reports in the literature currently that use the POP-Q, for example, or the Baden-Walker, either one, presume that women who have Stage 0 are things that are at normal levels in the pelvis or halfway to the hymen would be considered to

have a normal pelvic exam.

MR. NORTH: If you would mark this as the next exhibit.

(Defendant's Exhibit 7 marked.)

BY MR. NORTH:

Q Regardless of what you believe the recurrence rate was or is today with native tissue surgeries, would you agree that in the late 1990s and early part of the 2000s that the belief was there was a significant recurrence rate with native tissue surgery?

A There's a distinction that we made between a physical exam and a reoperation rate. So I believe that there are women who do not have perfect outcomes following surgery, but they're not reoperated.

And the number of women who have an exam that wouldn't be called perfect is certainly different than the number of women who have an exam, have symptoms, and have physical findings, all of which would suggest that she's a candidate for repeat surgery.

Q Well, regardless whether you define recurrence as symptoms or the need for reoperation or anything in between, would you

agree that the consensus view was that there was a significant recurrence rate after native tissue surgery back during that time frame, the late '90s, early 2000s?

MR. GARRARD: Object to the form of your question insofar as the use of the term "consensus view."

A What we reported, and we were one of the early ones to identify this, describe it, and give our personal experiences.

What we evaluated is various sites in the pelvis. You'll see that in the chart of the article you referred to about the editorial on support defects.

We looked at specific sites in the pelvis, the support for the urethra, the bladder, the top of the vaginal canal, the cul-de-sac and the rectum in an effort to determine is there some specific part of a reconstructive operation that is more or less effective than another part of surgery.

When we looked at our 81 women who had sacrospinous ligament suspension, for example. Sacrospinous ligament suspension was accepted, and still is, as a very effective

method for treatment of the top of the vaginal canal or apical loss of support.

What we learned in reviewing our patients is, in fact, it is very effective for treatment of the top of the vaginal canal.

The anterior compartment, the support for the bladder, is the area that is most difficult to manage effectively from a surgical standpoint.

What we know now is that other physicians have identified the same thing. When they critically look at their own outcome from surgery and look at specific parts of the pelvis, most skilled surgeons have very good success with apical support, support in the posterior compartment. The dilemma is in the management of the anterior compartment in the anatomy.

What we know now also is from looking at large groups of women who have not had surgery that, in fact, if you take all women, examine them and describe the sites of the pelvis where they're most likely to have poor support, it's the anterior compartment of the bladder.

So women who had no surgery, that's most likely to be the area that will have poor support. Women who have had surgery, if they have an area in the pelvis where the support is sub-optimal, it is more likely to be the area by the bladder than any of the other parts of the pelvis.

We have shown that in sacrospinous ligament suspension. What difference does that make? It makes a difference because if you identify something that doesn't work as well as you would like it to work, you can then employ a strategy to try to correct that, such as modify your surgical technique.

In this case, what we chose to do is use a different approach to the treatment of prolapse with specific attention to the anterior compartment.

The people that are advocates of sacrospinous ligament suspension have modified part of the way they manage the surgery in an effort to reduce the persistence or recurrence of tissue in the anterior compartment.

When you look at women who have been evaluated after surgery, that's in one of the

charts also in that editorial, you can review several things. The anatomic outcome, the functional outcome, the sexual outcome, the quality of life.

But let's talk specifically about surgery, for example. If you have an operation for poor support, in your case it can be an inguinal hernia, in a woman's case it may be pelvic, poor support. For a doctor to provide an effective operation, they have to know what you have and employ a technique that is going to be effective.

So in the outcome of hernia surgery, the things that we look for are the cure and the durability. Is it cured and how long does it last.

At the six-weeks visit after surgery, if a patient returns and their examination is normal, you can infer that the person caring for that patient saw what was the matter and executed the procedure effectively to take care of the issue.

If someone returns at six weeks and their examination isn't normal, we'll use these patients that you referred to in that chart of

mine.

At six weeks when the patients came back, 94 percent of the women had a normal exam. The inference is that we saw and corrected what was the matter.

At a subsequent visit, more of these women had poor support than they did at six weeks. The implication for that is the procedure wasn't durable. It wasn't that something failed to be repaired, it either wasn't durable, or in the case of sacrospinous ligament suspension, the operation predisposed the woman to some other loss of support.

We have several examples in GYN surgery where one operation may dispose you -- predispose you to the acquisition of another loss of support.

The six-week visit's helpful because at the six-weeks visit you can make an estimate did the doctor see and do what was appropriate.

If the six-week exam is abnormal, one of several possibilities. The person did not see properly and identify what should have been corrected. They saw it and corrected it, but it wasn't durable enough even to last six

weeks. They saw it and corrected it and there was some perioperative event that predisposed the operation not to work. Collection of blood in the incision, suture materials that broke. There are a variety of things that could happen.

But the six-weeks visit is helpful to sort out the technical aspects of was the surgery performed correctly for the right indication.

The longer term follow-up gives you a much better clue about was this operation durable. And if it isn't durable, why isn't it and what can you do to try to make it more durable.

Plastic surgery is a perfect example because everyone can see it. If you know someone who's had plastic surgery, for example, in their face, which is the most obvious place to see it, there's a recovery phase where someone who's had plastic surgery doesn't want to be seen in public because there's bruising, swelling, tenderness, all of those things which would go along with any surgical therapy.

Once they recover, ideally they're

going to look differently than they did before. If you see a woman or a man or a child who has had plastic surgery at six months after surgery, they may have a wonderful outcome. When you see them five years later or some other time in the future, the outcome isn't as likely to be the same as it was in that early perioperative period.

All surgery that is reconstructive in nature has durability as an issue.

MR. NORTH: With all due respect, Doctor, I'm going to object to the answer as nonresponsive to the question.

BY MR. NORTH:

Q The question was very simple.

MR. GARRARD: And I think he answered your question.

BY MR. NORTH:

Q In the early -- late 1990s, early 2000s, let me put it this way, did -- was the belief or what was being shown in the medical literature that the recurrence rates for native tissue surgery were high?

A At the time you're asking me about, the article referenced by Ambrose and Amanda

Clark in 1997, stimulated this concern about reoperation rate for surgery.

Q Okay.

A As I've told you, the reoperation rate was for more than prolapse.

Q Now, if you would look at Exhibit 7. This is an article you wrote in 2005; is that correct?

A Yes.

Q And what was this published in?

A The International Urogynecologic Journal.

Q And your coauthor was Mickey Karram?

A That's correct.

Q And who is he or she?

A Mickey Karram is a physician in Cincinnati who is specialized in treating -- evaluating and treating women who have disorders of the pelvic floor.

Mickey has been editor of this journal. He is not currently. He has been editor of the journal. He has been president of our major societies, and he is the director for a fellowship program in female public medicine and reconstructive surgery. And is

the coauthor of what's considered to be one of our standard texts in this field.

Q And this article sort of generally discusses the fact that there are new technologies being introduced to the market during this time frame in 2005 for the treatment of pelvic organ prolapse, correct?

A Yes.

Q And some of those new technologies would be the transvaginal mesh products for the treatment of prolapse?

A Yes.

Q And in fact, towards the end or at the very end of the article, you and Dr. Karram state that: As a patient advocate, however, we all must decide whether to embrace new technologies or products early in their development phase or to wait on appropriately performed trials to understand the risks and benefits of each procedure. These are the decisions that we, as pelvic surgeons, will have to make.

Correct?

A That's exactly what it says.

Q And the truth of the matter is that a

number of pelvic surgeons at that time frame made the choice to use some of these new technologies, correct?

A Yes.

Q And in fact, they have -- were used in the 2005 to 2008 time frame, let's say, fairly widely in the gynecological surgery community, weren't they?

MR. GARRARD: Object to the form of the question so far as you use the term "fairly widely."

A They were used. I don't know the percentage of patients who had reconstructive surgery had a mesh product used or not.

BY MR. NORTH:

Q Fair enough, Doctor.

You would agree with me that a number of surgeons that you respect in the gynecological community throughout the country have used these products, correct?

A I have a lot of associates and/or friends who do the same thing that I do because this is a relatively small number of physicians in general.

There are multiple ways to do

everything. On one end of the spectrum, I and a certain number of people primarily would use native tissue surgery. On the other end of the spectrum, there's someone who would be more likely to use a product. And then there's everything in between.

Q And there are people on the other end of that spectrum in your rather narrow field that you respect, correct?

A There are many.

Q Dr. Lucente, for example, he uses these products, doesn't he?

A I can't tell you which ones. He's been a spokesman for J&J and I don't know for whom else, but --

Q Okay.

A -- yes.

Q And a number of your colleagues at ACOG or AUGS, A-U-G-S, have used these products over the years, correct?

A I'm sure they have.

Q Have you read the article A Time To Rethink?

A I have.

Q And --

A By a group who are advocating for more -- a slower approach to the FDA recommendations on being concerned about mesh products.

Q And in fact, the authors or signed -- people that have signed on to the Time To Rethink article, see surgical benefits in the use of these transvaginal mesh products, don't they, in certain patients?

A I'm sure they do. I don't recall the details of the article. But I'm sure they feel that there are benefits to use of products in particular cases.

Q And a number of the physicians that have signed on or endorsed the Time To Rethink are people that you respect in the field, correct?

A I can't tell you who all signed on. There are some of them I know I respect them. There's some I don't know.

Q Other than the article we just discussed, Exhibit 7, do any of your other publications refer or discuss in any detail transvaginal mesh products for the treatment of prolapse?

A Yes. There is one that may not be in my CV, although, I thought it was, relating to The Perfect Storm.

Q The Perfect Storm?

A Yes.

Q Not the movie, I assume?

A Not the book. It's not about deep sea fishing. Although, it could be.

Q Let's see, where did your CV go.

MR. GARRARD: There's a copy of it.

BY MR. NORTH:

Q Here, it is.

Could you point that out to me?

A I will if it's here. It isn't on here. It was published in the last year or two in the International Journal. Margaret probably can find that if you would like to get it. We'll have somebody get it and give it to you. It's indexed.

Q It's called A Perfect Storm?

A I believe that's correct.

Q And published in the International Journal of what?

A International Urogynecologic.

THE WITNESS: And I believe,

Margaret, it was in 2012.

MS. THOMPSON: Yeah, I have it.

THE WITNESS: If I'm not mistaken.

BY MR. NORTH:

Q Did you have any coauthors on that article?

A Dr. Brubaker, I believe.

Q Brubeck?

A Brubaker, B-R-U-B-A-K-E --

Q Linda Brubaker?

A Yes.

Q Have you consulted with Dr. Brubaker over the years?

A About what?

Q Anything in the practice of your field.

A Well, Dr. Brubaker and I, one, are good friends. Two, we work together in many organizations. We have lectured together, taught together, traveled together, discussed patients together. I think the answer to that would be yes. We've written articles together.

Q Dr. Brubaker is an advocate against the use of transvaginal mesh for the treatment of prolapse, correct?

A I don't know. Did she classify herself as that? I haven't given her that title.

Q She does not believe in the use of transvaginal mesh for the treatment of prolapse, does she?

A I don't know how her practice is with that, frankly. I know that she probably wouldn't use it commonly. I don't know if she uses it at all. She has several associates.

MR. GARRARD: Here's the article if you want it. We can get other copies made.

Do you want to take a second and get other copies, Richard?

MR. NORTH: Yeah.

VIDEO TECHNICIAN: Want to go off the record, sir?

MR. NORTH: Yes.

VIDEO TECHNICIAN: Stand by, please.

We're off the record. The time is 11:28.

(Recess taken.)

(Defendant's Exhibit 8 marked.)

VIDEO TECHNICIAN: We are back on the record. The time is 11:30.

You may continue.

BY MR. NORTH:

Q Dr. Shull, while we took that brief break, we came up with the -- found a copy through Margaret of the other article you published regarding transvaginal mesh products?

A Yes.

Q And it's called A Perfect Storm?

A Yes.

Q And it was -- you were a co-author with Linda Brubaker?

A Yes.

Q And this was published in 2012?

A Published online November 16th, 2011. The hard copy was in 2012.

Q When were you first retained to be an expert witness in this litigation?

A I think the first time Margaret and I talked was April or May of 2012. Because I have one letter that came sometime in May.

THE WITNESS: So I think I must have talked to you in April, maybe.

MR. NORTH: Is -- she can't answer the questions on the record.

BY MR. NORTH:

Q Prior to that, did you have any conversations with Margaret or with Mr. Garrard or anybody from his firm about possibly getting involved in the litigation?

A No. In truth, I wasn't even familiar that litigation --

Q Now --

A -- was going forward.

Q Okay, fair enough.

Is it correct that the article we discussed a few moments ago, Exhibit 7, and then this article, Exhibit 8, are the only two publications you have regarding transvaginal mesh products, correct?

A Yes.

Q Now, in looking through Article 8, it appears that the position taken by you and Ms. -- or Dr. Brubaker was that the use of transvaginal mesh products can be effective in the hands of very highly skilled surgeons, but may not be effective or may be prone to complications in the larger surgical population or surgical troops?

A Are you asking me is that in this

article?

Q Yeah.

A May I read it just a moment --

Q Sure?

A -- and then I'll answer that for you.

(Witness reviews document.)

I believe what Linda and I stated is, we could assume that there are a group of people who maybe are able to use mesh-based procedures effectively, understand the complications of how to manage them, and would know which population of women would be suitable candidates. I think that's what you asked me.

Q Yes.

Are you familiar with Dr. Patrick Culligan?

A Yes.

Q Do you respect him as a gynecological surgeon?

A Yes.

Q What about Dr. Neeraj Kohli?

A Yes, I know him.

Q Do you respect him as a urogynecological surgeon?

A Yes.

MR. GARRARD: You asked him a question if he had any other articles on mesh, there is another article on mesh.

A Oh, I beg your pardon, I was thinking about the editorial. I beg your pardon.

BY MR. NORTH:

Q Mr. Garrard just indicated to us that you had a third article on mesh, and this is entitled A serious complication following placement of posterior Prolift, correct?

A That's accurate.

Q And this is a case report regarding a single patient?

A That's accurate.

Q And it involves Prolift, which is the Johnson & Johnson mesh implant?

A Yes.

Q It was published in 2009?

A Yes.

Q What was the complication there?

A In this particular patient, she is a, I believe, 32- or 34-year-old woman. I haven't read that recently. She's a young woman who was referred to our practice with rectal

bleeding.

On examination, she was found to have a fistula between the rectum and the vagina. It was noted to have a mesh product that had eroded into the rectum.

In this particular circumstance, I personally called the office of the surgeon who had performed the primary surgery, I did not speak to that surgeon because he was out, but I spoke to one of his colleagues and was told that Prolift was used and that this particular physician had used Prolift as a product of choice for prolapse.

I believe the surgery had been done -- I believe in the same calendar year, but I would have to read the article again to see. I don't know that for a fact.

So the woman had a laparoscopically-assisted hysterectomy. She had a mesh kit procedure for prolapse and then developed a rectovaginal fistula requiring removal of the mesh, and ultimately several operative procedures.

Q Okay. With the addition of this third article to the mix, is that now all of

the articles you've ever published with regard to transvaginal mesh products?

A I believe it is, and I apologize for not remembering that. There is an article which we have published that doesn't involve our placing mesh transvaginally. It will come when my new CV comes.

There's an article involving 25 patients in my practice who had prolapse of the vagina following an abdominal sacral colpopexy.

We operated on those women transvaginally. In approximately half of them we could identify the mesh from the sacral colpopexy, it was still attached to the sacrum, was not attached to the vagina. And we left that mesh in place, placed sutures in it and used it as a part of the suspensory mechanism for the corrective surgery which I did.

The concept behind that case series was to describe our experience with women who had failed an operation which is felt to be reliable, and all surgeries have a failure rate. That the failure frequently occurs where the mesh is detached from the vagina, not the sacrum. And if you can identify the mesh and

it's in place, not infected, it could become -- it could become a part of the suspensory mechanism.

THE WITNESS: If that's my updated CV, that should be...

MR. NORTH: No, it's not.

MS. THOMPSON: No.

MR. NORTH: Could you mark this as Exhibit 8 -- or, I guess, we're at 9?

THE COURT REPORTER: Uh-huh.

MR. NORTH: Yeah, 9, please.

(Defendant's Exhibit 9 marked.)

A There's an article you've asked me about before regarding the Prolift.

MR. NORTH: This is the one he's talking about Prolift.

A The Prolift.

Is a single patient. And the reason we reported that is because we felt that the complication was significant enough that it warranted general knowledge about it.

BY MR. NORTH:

Q And we have now marked as Exhibit 9 there the Prolift article you were discussing, correct?

A Yes.

Q And then you mentioned a fourth article that concerns mesh that you've seen when you're going in for a surgery on certain patients.

A Yes. And it's not related to a complication of mesh, it's related to patients referred to me who had had a sacral colpopexy, they had a recurrence of their prolapse, they wanted to have further surgical therapy. I chose to operate on vaginally. In about half of those women, I could use the existing mesh as a part of the reconstructive surgery.

Q None of these four articles that refer to mesh specifically deal with Avaulta mesh, correct?

A That's accurate.

Q And none of these articles deal with any product manufactured by Bard to your knowledge?

A There are no ar -- there are no products named in the two editorials. Prolift is identified in the case report. And in the series of sacral colpopexy failures, no products were mentioned by name on that because

I don't -- I didn't know the names of the products.

Q Now, to your knowledge, have we now discussed all of your publications with regard to mesh products for the treatment of pelvic organ prolapse?

A I hope so.

Q Okay.

MR. GARRARD: Do you need to look at the new CV?

MR. NORTH: Well, he can always --

MR. GARRARD: Well, I'm just -- we may --

MR. NORTH: -- add something. I'm just asking to his knowledge now.

BY MR. NORTH:

Q Let's talk a little bit about your retention in this case as an expert witness.

Now, I certainly understand -- you know, appreciate your expertise as an OB-GYN and in the gynecological surgery area. But I want to see if we can be clear about areas where you're not an expert. And I asked you about your training and expertise in some of these areas earlier.

But would you agree that you are not an expert in developing warnings and labels for medical devices?

A I have never developed a warning or a label. I don't intend to do that. And I don't know the process for doing it, so I would not claim to be an expert in that area.

Q And you are not an expert in the design of medical devices, are you?

A No, I've never designed a device.

Q And you are not an expert in biomaterials?

A No.

Q And are you an expert in biocompatibility?

A No.

Q And are you an expert in materials manufacturing?

A No.

Q Are you an expert in the manufacturing processes for medical devices?

A No.

Q And we talked about your training in pathology. Would you consider yourself an expert in pathology?

A No.

Q Would you consider yourself an expert in toxicology?

A No.

Q Would you consider yourself an expert in the marketing of products?

A No.

Q Would you consider yourself an expert in the marketing of medical devices?

A No.

Q Do you deal with sales representatives from various medical device manufacturers as a part of your practice?

A Sometimes.

Q Do you deal with any medical device or any sales representative from Bard?

A Can you tell me what dealing with means?

Q With any type of product.

A Do I sit down and discuss the products with them?

Q Uh-huh.

A Perhaps I have. I certainly wouldn't do it with any frequency.

Q Do you know the name of any Bard

sales representative assigned to your facility?

A No. If you gave me someone's name, I may recognize it. I would not be able to tell you someone's name.

Q Okay. Well, as you sit here today, do you have a specific recollection of having sat down and talked with a Bard sales representative in the past?

A Regarding?

Q Any Bard products.

A I don't know the answer to that. I may have, but I cannot tell you when or what the product was.

Q Do you consider yourself an ethicist?

A Can you tell me what that means?

Q An expert in ethics.

A Well, I don't lecture in it. I feel that I know the concepts of what it is to be ethical and use them in my practice.

Q But you have no particular training in that, do you?

A I have not had a specific education in ethics. We are required in Texas to have so many continuing medical education hours per year that relate to the ethics of medicine to

maintain our license. And I believe it is one or two hours per year of continuing medical education that is related to the ethics of medicine.

Q Do you consider yourself an expert in regulatory affairs?

A No.

Q Do you consider yourself an expert in FDA procedures and processes?

A No.

Q Are you an engineer?

A No.

Q Have you ever conducted any testing, other than the visual observation of explanted material on any transvaginal mesh implant for the treatment of prolapse?

A No.

Q Have you ever done any comparative study with -- between the various manufacturers' transvaginal mesh implants?

A No.

Q Have you ever seen a product that you knew to be Avaulta Plus?

A Yes.

Q And what was the context of that?

A I saw the prepackaged product, opened the package, felt the product, looked at it, handled it, but I haven't implanted it in anyone.

Q And have you done the same with the Avaulta Biosynthetic and the Avaulta Solo products?

A I've looked at all of -- yes, I've looked at all of those.

Q Were those products furnished to you by the Plaintiffs' attorneys in this litigation?

A Yes.

Q Prior to your involvement in this litigation, and having seen those products as furnished to you by the attorneys, had you ever seen the Avaulta products that you know of?

A That's a very good question. I can't tell you the answer to that for sure, because I probably have.

And the reason I would say that is that at the majority of the professional meetings I go to, vendors are present and demonstrating what they have.

So I frequently go by the vendor

stands to look at what they have to sell, to read their information or to talk to someone who is there to describe it.

So, even though I can't tell you the circumstances of which I did see it, I believe that that would be true because I normally make an effort at the meetings to go by and see what each company has.

Q So you believe you may have seen the product before because it is your general practice to stop by manufacturers' booths at trade organizations -- or at organizational meetings and for you to just see what they have to offer right now?

A Yes.

Q But as you sit here today, do you have a specific recollection of having done that with the Avaulta products?

A No.

Q After being furnished the products by the Plaintiffs' attorneys in this litigation to look at, have you had any other occasions subsequently to look at those products?

A No.

Q Now, when you looked at those

products, you didn't do any testing of any sort on them, did you?

A No.

Q Did you read the instructions for use that came with the product?

A Yes.

Q Remind me what your fee is for your services.

A The fee that I'm being paid now is $500 an hour.

Q Did you bring your billing records with you?

MR. GARRARD: We have.

A No.

MR. GARRARD: We have them.

MR. NORTH: Can I see them?

A No, they have them, I don't have them.

MR. NORTH: My colleague, Ms. Cohen, thinks you are purposefully hiding all of these billing records.

MR. GARRARD: She sees worms under every rock.

MR. MOELLER: Please strike that from the record. I don't want to be any part of

that.

(Off-the-record discussions.)

MR. NORTH: Can you mark this as the next exhibit?

(Defendant's Exhibit 10 marked.)

MR. GARRARD: Do you want to mark the flash drive that we gave y'all?

MR. NORTH: We will.

MR. MOELLER: Yeah, I don't want to be the custodian of that.

MR. GARRARD: I don't want you to either.

MR. NORTH: Why don't you mark this as No. 11.

(Defendant's Exhibit 11 marked.)

(Off-the-record discussions.)

BY MR. NORTH:

Q Let me show you what's been marked as Exhibit 10 to your deposition, Dr. Shull. Is that a complete copy of your billing records thus far --

A Yes.

Q -- in this litigation?

A Yes, it is.

Q Let's go through those a moment. And

you said your rate was $500 an hour, correct?

A That's accurate.

Q Your initial bill was for -- on June 4 for $3750, correct?

A That's accurate.

Q So what was that approximately, seven hours?

A It would be seven and one half hours.

Q And then your next bill was on July 27th and that was for 1,460, correct?

A That's accurate.

Q And how many hours was that for?

A 2.92.

Q 2.92 hours, okay.

MR. GARRARD: Richard only bills in half hour increments, Doctor.

MR. MOELLER: Thought it was full.

MR. GARRARD: Huh?

MR. MOELLER: Full hours only.

BY MR. NORTH:

Q On August 23, you submitted an invoice for $11,875; is that correct?

A Yes.

Q And how many hours was that for, Doctor?

A 23.75.

Q And then on October 15 you submitted an invoice for 8,250; is that correct?

A That's accurate.

Q And how many hours did that reflect?

A 16.5.

Q So if I am computing this correctly, by October 15 you had billed for 50.77 hours, does that sound correct?

A I didn't do the arithmetic, but I trust you did.

Q That's dangerous to trust me with math.

But I believe that is correct. Does that sound about right?

A It's about right. I'll be glad to add it if you would like me to.

Q And your report was submitted on October 15 of 2012, correct?

A I cannot give you the exact day. Yes, in mid-October. I don't remember the exact day.

Q So is it fair to say, Doctor, that prior to the submission of your report in this case, you had spent roughly 50 hours reviewing

the documents provided to you by the Plaintiffs' attorneys, reviewing the medical records of the various Plaintiffs that you have received, meeting with the Plaintiffs' attorneys on several occasions, and finalizing your report in this case?

A That's accurate.

Q How many times did you meet with the Plaintiffs' attorneys prior to October 15 of 2012?

A At least six times according to this -- these invoices.

Q And when you --

A I don't know if there's another, but I see six times.

Q And when you would meet with the Plaintiffs' attorneys, you would charge for the time that you spent meeting with them, correct?

A That's accurate.

Q And at the times you met with them, you didn't actually review these documents while you were meeting with them, did you? Or did you?

A We may have referred to them.

Q But --

A Are you asking did we simply talk with one another without the -- looking at any records?

Q No. I guess what I'm saying is, you didn't go through these documents one by one during those meetings, did you?

A No, that wasn't the purpose of meeting with them. I did that preparation in advance.

Q Okay. And then to complete your billing records, I believe that on December 10 you billed $4,000, which I assume would be eight more hours, correct?

A That's accurate.

Q And then on January 21 you billed 9,875?

A That's accurate.

Q And how many hours would that reflect?

A 19.75.

Q And how much time have you spent on this matter since January 21?

A That's a good question. I was on holiday in Hawaii for one week. I spent part of my time there reviewing records. I spent

yesterday here and today. And a few hours on Monday at my house. So I don't -- I haven't added all of that up.

Q Are you -- have you been designated as an expert witness in any other litigation regarding mesh?

A No.

Q Other than the attorneys representing the Plaintiffs in this case -- well, and first, tell me which attorneys have you spoken to about this litigation.

A This specific litigation?

Q Yes.

A I've spoken to Mr. Garrard.

Q Right.

A Dr. Thompson. Mr. Mueller and Mr. Matthews.

Q Okay.

A I don't think there's anyone else.

Q Have you spoken with any of the other experts retained by the Plaintiffs in these cases?

A No.

Q Have you reviewed any of the other experts' reports in this case?

A The depositions, not the reports.

Q Which depositions of experts did you review?

A Dr. Raybon, Dr. Miklos, Dr. Kaminski, Dr. Margolis, Dr. Nutt, Dr. Barber, Dr. Barbee, Dr. Visco. I'm trying to remember if there was someone else.

Q Well, let me just ask this. Have you reviewed the deposition of Dr. Altenhofen?

A I don't recognize that name.

Q Dr. Carroll?

A No.

Q Dr. Loving?

A No.

Q Dr. Hoyte?

A No.

MR. NORTH: H-O-Y-T-E.

BY MR. NORTH:

Q Dr. Brennan?

A No.

Q Dr. Zolnoun, Z-O-L-N-O-U-N?

A No.

MR. GARRARD: Richard, to save you time, he hasn't been furnished the depositions of any experts that we have engaged.

MR. NORTH: Okay.

MR. GARRARD: He has reviewed the treating and implanting doctors' depositions that he told you about, and there may be another one or two that he didn't list.

BY MR. NORTH:

Q Have you spoken with any of those doctors that treated the Plaintiffs?

A No.

Q Have you spoken with any of the Plaintiffs in this litigation?

A No, I've never met one.

Q Have you ever spoken besides -- other than a possible conversation with the Bard sales representative assigned to the Temple territory, have you ever spoken with a Bard employee before?

A Unless it would be at one of these meetings where someone who is representing the company at a national meeting and I wouldn't have remembered who or where, so I could have then.

Q But you don't have a specific recollection of having done so?

A No.

Q What about with regard to Sofradim?

A No.

Q What about with regard to Tissue Sciences Laboratories?

A No.

Q Did you read any depositions of Bard employees taken in this litigation?

A I read excerpts -- I must have read excerpts from something because they're in the report. I don't know if that's -- if one of those was from a deposition or if that was all e-mail.

I don't remember seeing a deposition from a Bard employee. And I don't believe that any of these references came from a deposition. I guess you would know that better than I.

MR. GARRARD: He has looked at some employee depositions and they're reflected in his report.

BY MR. NORTH:

Q Were you furnished entire copies of the depositions or only excerpts of them?

A That's a good question. I don't know the answer to that. I don't remember having an entire deposition from anybody from Bard.

MR. GARRARD: He did have whole copies.

THE WITNESS: Whose was that? I don't remember that.

MR. GARRARD: Well, you had -- I can think of right now Orr and --

BY MR. NORTH:

Q Oh, the depositions you were provided, are they here in front of you?

MR. GARRARD: I'm sorry, what was your question?

A Are you asking me about the physician treaters and whatnot?

BY MR. NORTH:

Q No, I'm asking about Bard employees. Where would those depositions be?

A I don't know the answer to that.

MR. GARRARD: They're on the flash drive, aren't they? They're on the flash drive.

MR. NORTH: I'm going to remove the sticker for just a minute.

THE COURT REPORTER: I'll remember it.

MR. GARRARD: Keep your eye on him.

MR. NORTH: Just one second, Doctor.

If I could ask, counsel, Doctor, in particular, would the depositions have been produced as pdfs on here?

MS. THOMPSON: Probably.

MR. GARRARD: I've got them right here. Would it assist you if I told you which one's, Richard?

MR. NORTH: Yeah. I mean, under what file are they? I'm seeing the Plaintiffs.

MR. GARRARD: Under -- they were the ones that was furnished to him, David Ciavarella, Jennifer Gordon Mercuri, Jim Ross, John Knorpp and Robert Orr.

MR. NORTH: I'm just trying to figure out where they are.

MS. THOMPSON: They're under -- I think they're under Bard depos if you see that.

MR. GARRARD: This is how they're listed on mine. Is that how it would be?

MR. NORTH: On this flash drive there is nothing called Bard depos. There are files called Bard Plaintiff depos, Bard treater depos. I've looked at both of those, the employees are not there. There's another file

called photos, and then there are a list of pdfs.

MS. THOMPSON: Let me check that out for you. I'll be right back.

MR. NORTH: Mr. Garrard, could you read on the record again the depositions of Bard employees that you gave to Dr. Shull.

MR. GARRARD: I sure will. Do you see a category titled Full Cited Depositions on there?

MR. NORTH: Uh-uh.

MR. GARRARD: No. Well, then we've got a transfer problem on that thing, I guess.

It's Ciavarella, Jennifer Gordon Mercuri, Jim Ross, John Knorpp, and Robert Orr.

MR. NORTH: Ciavarella, Mercuri, Orr, Knorpp.

MR. GARRARD: Ross.

MR. NORTH: And Ross.

MR. GARRARD: Uh-huh.

A Actually, I remember reading Dr. Ross when you asked me about Bard employees, I believe. I guess I didn't associate Dr. Ross with a Bard employee.

BY MR. NORTH:

Q Right, and that's -- fair enough.

Did you review these depositions electronically or did you have hard copies of them?

A I had -- everything that I had in this report, 26, came in hard copy. With the -- when I told you I looked at the deposition for the treating doctors, I started off on hard copy. But then I sat down and looked at them on -- electronically instead because the books were too big.

Q Well, you were furnished a hard copy of the employee depositions at some point, the ones that Mr. Garrard just listed or do you recall?

A Well, did I have the whole thing? I don't -- I don't remember the answer to that, if I have their whole deposition or not.

Q Do you recall anything specific from Dr. Ciavarella's deposition?

A If I look back at what I read, I will. Without looking at the record. Do you have something specific you would like me to --

Q No, I'm just -- as you sit here, without looking at anything, is there anything

that comes to mind specifically about Dr. Ciavarella?

MR. GARRARD: Object to your -- I object to your question in form. He's got a lengthy expert report where he has mentioned a number of things, including Ciavarella.

I don't think that's a fair question to say, as you sit here, do you remember something.

MR. NORTH: Well, you can ask that with the courts.

MR. GARRARD: If you need to look at your report, Doctor, look at your report.

A I'm happy to look at that and then see if there's something --

BY MR. NORTH:

Q Well, I don't need to look at that. I just need you to answer the question.

MR. GARRARD: Well, he can look at his report if it assists him in answering the question.

BY MR. NORTH:

Q Well, he can answer the question correctly, if the question is, without looking at your report, do you recall anything

significant from Dr. Ciavarella's deposition?

MR. NORTH: You can object to it as unfair and take it up with the court, but it's a fair question in my view.

MR. GARRARD: I do object to it as an unfair question without him having the opportunity to look at his report.

A I believe that I remember something about him, but I cannot tell you all of the details. I believe that Dr. Ciavarella would be one who had questions about the safety and efficacy of the products, and one of the discussions about the development of a product.

BY MR. NORTH:

Q But you've never spoken with him?

A I wouldn't know him if he came in.

Q You were not shown the deposition of Dr. Scott -- I mean, of Mr. Scott Britton, were you?

A I don't believe I was.

Q And you weren't shown the deposition of Laura Bigby?

A I don't think so.

Q And you weren't shown the deposition of Adam Silver?

A I don't believe so.

Q And you weren't shown the deposition of Tad Nations?

A I don't believe so.

Q You weren't shown the deposition of Melissa Johnson?

A I recognize that name. I don't know that I saw her deposition.

Q The only depositions you've seen are the ones that Mr. Garrard and Dr. Johnson showed you, correct?

A You mean Dr. Thompson?

Q I'm sorry, Dr. Thompson.

A I believe that would be true.

Q And they selected the depositions to show you, correct?

A I presume they did.

Q I mean, you didn't come up with a list of the employees yourself that you wanted to see their depositions, did you?

A No.

Q Okay. As a part of your work in this case, have you gone back and looked at any regulations put out by the FDA that might govern these products?

A The 510(k) -- I've looked at the form for 510(k) submission.

Q And that was given to you by the Plaintiffs' attorneys, correct?

A Yes.

Q Have you looked at any regulations from the FDA, though?

A I have not gone to an FDA website or obtained any information from the FDA regarding how to submit a proposal or what's included or the process for it.

Q Well, the FDA regulations go beyond how to submit a proposal. So have you looked, as a part of your work at this case, at any regulations put out by the FDA that might be applicable to this product?

A No.

Q Have you reviewed the 2008 and 2011 public health notifications put out by the FDA?

A Regarding?

Q Pelvic mesh products.

A The warnings about pelvic mesh products?

Q The public health notification.

A Yes, I have.

Q Had you read those before you became involved in this litigation?

A Yes.

Q Have you -- you did not attend the advisory panels' meetings and hearings regarding these products in September of 2011, did you?

A I did not.

Q And have you read any transcript from those hearings?

A No.

Q Are you familiar with the difference under the FDA's processes between a 510(k) and a PMA?

A I don't think I could describe the differences to you for that.

Q Do you know what Bard was required by the FDA to show in order to get clearance to market the Avaulta products?

A I believe in general for 510(k)s any company has to show that the requested product or device is substantially similar to a predicate device.

So Bard had to find one or more predicate devices that were substantially

similar to the product they hoped to market and agree that their proposed product was substantially similar to these predicate devices.

Q What is your understanding of when the initial Avaulta product, Avaulta biosynthetic product was first introduced to the market?

A You're asking me what time?

Q Yes.

A I think about 2005 or '6.

Q In 2005, there were already transvaginal mesh products for the treatment of pelvic organ prolapse on the market from other companies, correct?

A Yes.

Q And there were actual kits, correct?

A Yes.

Q And were there trocar-based kits on the market at that time from other companies?

A Yes.

Q Were there kits or mesh implants with arms on the market at that time?

A I believe that every kit with a trocar has an arm or there wouldn't be a

trocar.

Q So by the time the Avaulta Biosynthetic was introduced to the market there were predicate devices already being sold, correct?

A There were products with trocars being sold, that's correct.

Q We talked about the -- your observation of Avaulta mesh in the past.

Have you ever looked at Avaulta under a microscope?

A No.

Q Have you ever measured its pore sizes?

A No.

Q And I believe you told us you'd done no testing with mesh before, so you've never done any degradation testing, have you?

A No.

Q Elasticity studies?

A No.

Q Shrinkage studies?

A No.

Q Do you -- or what is your understanding of the FDA's requirements with

regard to clinical studies before a product is introduced to the market?

MR. GARRARD: Object to the form of your question unless you delineate what type of products you're talking about.

What kind of product you talking about, Richard, because there's a difference?

MR. NORTH: I just want his general understanding.

MR. GARRARD: Well, no, you need to tell him what kind of product you're talking about. Are you talking about drugs, are you talking about mesh?

MR. NORTH: You can make an objection to the record.

MR. GARRARD: Well, I am making the objection, but, Richard, you need to tell him what type product you're talking about because there's a difference.

BY MR. NORTH:

Q What's your understanding of what the FDA requires with regard to clinical studies prior to the introduction of a product to the market?

MR. GARRARD: Objection to the form

of your question unless you define what you're talking about in terms of a product because that makes a difference.

MR. NORTH: Your objection's noted.

A Or if they're pharmaceutical items, they are, to the best of my knowledge, rigid requirements for testing pharmaceutical agents that go through a variety of efficacy and safety studies, including human information before they're approved to be sold.

In the case of products such as a surgical product, there are different classes of products. Some require very little information. A trocar, for example, may be in a class that requires very little information about it except, perhaps, the technical description of it and, perhaps, something about its composition.

Then as the classification of products increases, I believe this is true from one, two, or three, there are progressively more requirements for collecting and reporting information on indications, complications, management, safety, efficacy, and whatnot.

BY MR. NORTH:

Q With regard to medical devices, do you know what percentage of medical devices go through clinical studies before they're introduced to the market?

A No.

Q Do you know with regard to medical devices whether more products go through clinical studies or don't go through clinical studies before they're introduced to the market?

A I do not know that.

Q Do you know whether Bard was required to conduct clinical studies on Avaulta before introducing it to the market?

MR. GARRARD: Required? In terms of the form of your question, required by what or whom?

BY MR. NORTH:

Q By FDA rules and regulations.

A Do you mind repeating the question for me?

Q Do you know whether Bard was required under FDA regulations to perform clinical studies on Avaulta before it was introduced to the market?

A I do not know that. My presumption is if they're using the predicate device as the mechanism for getting the clearance, that there may have been no requirements.

Q How long do you believe it would have taken to conduct a clinical study of Avaulta, or do you know?

A I can answer that in general. It depends on what you would like to know about it. So depending on the knowledge you hope to acquire, there would be varying time intervals.

If it's a question about indications and patient selection, that may take a shorter time period.

If there are questions about the morbidity associated with the operation itself or the morbidity in the first six weeks following surgery, that would take a relatively defined time period depending on the number of patients required for you to draw conclusions from.

If you're talking about the long-term consequences of a product, in this case we have previous information from reports on sacral colpopexy, for example, which teaches us that

some of the adverse outcomes or adverse events are a function of time. And some of the adverse events never go away. And it's a question of how frequently they occur as the duration of time increases.

So let's use sacral colpopexy as an example. There are some cases where you can tell immediately on a perioperative morbidity or mortality, but the long-term information on exposure, erosion, bleeding, and whatnot, it takes years to acquire.

So to answer your question about Avaulta. Depending on the information that someone thinks is appropriate to know, it could take a long time and a lot of patients to learn that.

Q Do you know whether clinical studies were performed on the Johnson & Johnson TVT sling or the Boston Scientific stress urinary incontinence implant you used before the time you began using them?

A Before the time I began using tension-free vaginal tapes by Johnson & Johnson, the product had been cleared for sale in the U.S. for about five years.

I do not know what was required prior to the clearance of the product, but I know that the reason I waited to use the product is that in a 5-year interval there were reports about its safety and efficacy which had been published.

Plus, I had the opportunity to talk to a number of people around the world who had experience using the product.

And my entire reason for waiting as long as we did was to learn more about that because in the history of gynecology specifically there have been a number of products introduced during my practice lifetime which have unintended consequences and the products have been met with a great deal of enthusiasm. And after a certain time period that enthusiasm diminishes.

And in fact, some of the products are no longer available. In the case of urinary incontinence, for example, we already had examples of that with Protogen. So we knew that there could be unintended consequences of products. And before that, Gortex used for a sling.

So we already had examples of procedures being advocated, enthusiasm being generated, and then reality setting in where the enthusiasm died off significantly.

IUDs, for example, were taken off the market entirely because one particular product had unintended consequences.

So based on all of those things, I was interested in waiting until more information was available.

Q But do you specifically recall whether or not there was -- had been clinical studies performed by the time you began using the J&J stress urinary incontinence product or by the time you started using the Boston Scientific product?

MR. GARRARD: Objection, asked and answered.

A I know that there were case series, surgeon experience, there were cohorts of patients that were followed.

I don't remember the year the article was published by Paul Hilton and his associate comparing the Burch colposuspension to the tension-free vaginal tape looking at morbidity

and efficacy. That occurred sometime in early 2000s. So it would have been about the time that we began using the product.

BY MR. NORTH:

Q Do you know if -- can you identify any randomized controlled trials that were performed on the Johnson & Johnson or Boston Scientific products before the time you started implanting them?

A No, I do not know that.

Q When did you first start performing native tissue surgery?

A I did my residency from 1968 to 1973. I began getting opportunities to operate during the residency program during my second and third and fourth years. So that would have been in 1971, '2 and '3.

Q At the time you first began performing native tissue surgeries, were there randomized controlled trials published concerning that surgical technique?

A I'm trying to think if there's even another situation where that could have occurred, because there were various types of native tissue repairs, but there weren't

repairs people were routinely doing with any supplemental tissue. So the answer to that is no.

MR. GARRARD: We've been going for about an hour and 45 minutes.

MR. NORTH: Yeah, I'm ready to go. I was just waiting for lunch.

VIDEO TECHNICIAN: Stand by, please.

And we are off the record. The time is 12:25. This is the end of Tape 2.

(Lunch recess.)

VIDEO TECHNICIAN: And we are back on the record. The time is 1:09. This is the beginning of Tape 3 of the videotape deposition of Dr. Robert Shull.

You may continue, sir.

BY MR. NORTH:

Q Dr. Shull, we were talking about testing before we took our lunch break.

In reading your report, I gather that you are critical of Bard's animal testing on its products?

A Yes.

Q Are you aware of what testing was done on the Sofradim Avaulta product?

A Do you have something specifically in mind that I should -- you're asking about?

Q No, I'm just asking, did you read anything about the testing done on the Sofradim Avaulta product?

A Not animal testing, no.

Q And you did not read the deposition of Dr. Michel Therin from Sofradim?

A No, I didn't.

Q What is your understanding of what types of animal tests were performed on the Avaulta Plus and Solo products?

A That in rats and rabbits, pieces of the material were implanted into the abdominal wall of the rat. And the rabbit, there could have been something in the vaginal canal. I can't remember about the rabbit.

And then in the sheep, there were four sheep that were studied. And each of those -- well, and the ones in the abdominal wall, for example, they clearly would have been placed without trocars.

I don't believe that any animal study tested the kit as a unit.

Q Is that your principal criticism of

animal studies, is that they did not study the entire kit in your view?

A There are several reasons to be concerned. That would be one.

Another is there's a limited amount of information that can be gathered on an animal study. Mainly, the information the investigators collect relate to the body's reaction to the implantation of a foreign material.

The material is implanted and then at some point in time it's explanted and the animal may or may not be sacrificed.

They're looking at qualities of wound healing, inflammatory changes, scar formation, other issues about which we'd be interested in clinical practice, for example, regarding effects on valve function, bladder function, sexual function, pain, quality of life.

Obviously, those can't be obtained in any animal model.

But a part of the concern is also testing the product without the entire system is a major concern.

Q Doctor, is it fair to say that your

criticisms of the animal studies is that they did not provide sufficient information in your view as opposed to any inherent flaw in the protocol or design of the study?

A Are the study designs flawed? It depends on what you want to know. So I'm not judging the study based on the study itself being performed improperly.

Can the study provide information that's clinically helpful is a whole different issue.

Q Did you review any animal studies of the Johnson & Johnson TVT sling or the Boston Scientific incontinence product you used before you began using those products?

A I did not.

Q Did you read the protocols for the Bard animal studies?

A I'm trying to remember if I read any of the protocols. I don't believe I did.

Q Did you read the published reports of the studies?

A I read -- I'll have to look in my files and see specifically what I read. And I'm not sure I have all of those with me.

MR. MOELLER: Do you want to concede or stipulate he did not review those?
MR. GARRARD: I'm sorry?
MR. MOELLER: Do you want to concede or stipulate he did not review the --
MR. GARRARD: No, I think he did review them.
MR. MOELLER: Oh, you think he did. I'm sorry.
A I'm looking for the reference here.
MR. MOELLER: Sorry about that. I was trying to expedite things.
MR. GARRARD: I know what you were trying to do.
A I'm looking for the reference harder so I can try to answer your question specifically.
MR. GARRARD: May I hand it to him, Richard?
MR. NORTH: What?
MR. GARRARD: I've got the one he reviewed if I may hand it to him without you getting upset.
MR. NORTH: Okay, this one time I'll let you testify for him.

MR. MOELLER: Did we figure out if our USB drive is complete or not?

MR. NORTH: It is.

MR. MOELLER: Oh, it is complete.

MR. NORTH: Uh-huh. I found -- well, I found those depos on there.

MR. MOELLER: Oh, you found it. Okay.

MR. NORTH: He gave me -- they're pdfs and he gave me the key numbers on them.

MR. MOELLER: I gotcha.

BY MR. NORTH:

Q Mr. Garrard just handed you a document, Dr. Shull; is that correct?

A Yes, he did.

Q Do you know what a Bates number is, the stamp at the bottom left-hand side on the first page?

A I believe that the Bates number is --

Q Right. Could you read that --

A -- on the lower right-hand --

Q -- for the record.

A On the lower right-hand, capital AVA2E0066011.

Q Can you tell us what that document

Mr. Garrard handed you is?

A The title is A Novel Mesh/Tissue Combination for vaginal prolapse in a sheep model, a pilot study.

Q Before Mr. Garrard handed that to you, do you recall seeing that document?

A Yes. I was simply trying to find it so I could answer your question specifically.

Q Did you read that document prior to submitting your report in this case?

A Yes.

Q Do you recall seeing any other test reports?

A Regarding? Did I -- did I see test results regarding what?

Q That performed by Bard on the Avaulta products.

A I did not read the reports on the rat studies.

Q Did you read the report on the rabbit studies?

A I did not.

Q So you read the sheep study but not the rabbit and rat studies performed by Bard in the development of the Avaulta products?

A That's correct.

Q And based on your previous testimony, it's my understanding that you have never yourself created a protocol for an animal study for a device; is that correct?

A That's accurate. That's correct.

Q In your report you state that there was no scientific basis for Avaulta, the concept, and that the mesh with arms and use of trocars represented a radical departure from previously described grafts.

Do you recall that?

MR. GARRARD: Could you tell me which page you're referring to, please.

MR. NORTH: Pages 7 and 8 and 9.

MR. GARRARD: Thank you.

A At the bottom of Page 7, what I said: At the time the Bard Avaulta Biosynthetic product was introduced, there was no credible scientific evidence that supported utilization of an armed, transvaginally placed polypropylene mesh. In fact, questions regarding the safety and efficacy were already apparent prior to the introduction of the Avaulta Biosynthetic and the Avaulta Plus and

Solo products.

BY MR. NORTH:

Q And then look over on Page 9. There you describe the concept as a radical departure, correct?

MR. GARRARD: Doctor, you certainly can look at Page 9, but read whatever you need to.

A I'm looking for that on 9, those words.

Yes, I see it.

These products and the procedures required for their use represented a radical departure from previously described grafts used in the pelvis, which had been used only in very select cases.

BY MR. NORTH:

Q But I think you previously admitted or told me that Bard's Avaulta was not the first product introduced to the market for transvaginal use that involved mesh with arms in the use of trocars, correct?

A I did. I also -- you didn't ask me if they were a radical departure either, you just asked me if someone else had used them.

Q So you believe all of these kits were a radical departure?

A Yes.

Q But you agree that Bard's was not the first kit like that on the market?

A Bard is not the first one.

Q In your report you also state in that section that questions regarding safety and efficacy with regard to Avaulta were already apparent by the time the product was introduced.

What is your basis for that?

A If I could read the context of that.

At the time the Bard Avaulta Biosynthetic product was introduced, there was no credible evidence -- scientific evidence to support utilization of an armed, transvaginally placed polypropylene mesh.

In fact, questions regarding the safety and efficacy of the referenced item, polypropylene and armed mesh products, was apparent prior to the introduction of the Avaulta Biosynthetic and the Avaulta Plus and Solo.

The basis for that is what you asked

me.

Q Yes.

A The basis was on conversations with other physicians who were seeing patients with complications, on case reports, on discussions at scientific meetings, and on observation of patients who had had surgery with mesh products.

Q Were you aware of things like that as of 2005?

A Yes.

Q So by the year 2005, you had already determined that the safety and efficacy of transvaginal kits for the treatment of pelvic organ prolapse, that there was questions about their safety and efficacy?

A Yes.

Q When did you first make that determination?

A I think I told you earlier that on several occasions I was invited to sit in on roundtable discussions as J&J and perhaps someone else was interested in developing products to use mesh for prolapse repair.

And at the time those groups met, I

raised these very issues, placing a synthetic material in a clean contaminated field, of using trocars through spaces where we normally would not operate, of the possibility of injuries to structures we can't see, of how you could identify to manage an intraoperative complication, and what the long-term outcomes would be based on our knowledge specifically of sacral colpopexy.

Q Can --

A So...

Q Oh.

MR. GARRARD: Finish your answer.

THE WITNESS: That's it.

BY MR. NORTH:

Q Can you cite me any article, medical article in the literature prior to 2005 that raised safety or efficacy concerns about these transvaginal mesh kits?

A Can I give you one now with a title and reference, no. Can I find one? I'll be happy to look for one and tell you about it.

Q But just so I'm clear, as you sit here right now, you cannot name an article that predates 2005 and questions the safety and

efficacy of these kits?

A I do not have the author or the reference for that, that's correct.

Q Have you seen anything that indicated to you that Bard had questions about the safety or efficacy of the Avaulta kits prior to 2005 when they were introduced to the market?

A Have I seen a document where these questions were raised by employees of Bard?

Q Yeah, prior to 2005.

A I see on Page 13 in my report, beginning at the bottom of Page 12, Known problems with polypropylene should have alerted Sofradim and Bard to potential problems with its use in the vagina.

Q I'm sorry, read that again or tell me where you are.

A I'm at the bottom of Page 12, beginning of Page 13. Known problems with polypropylene should have alerted Sofradim and Bard to potential problems with its use in the vagina.

It appears that, as early as 2003, Sofradim knew there were problems with polypropylene mesh. In a document from

May 2003, polypropylene -- then the various trade names, Prolene, Marlex, SURGIPRO, Atrium -- when compared to polyester, was described as "more rigid and more aggressive with the tissues (a barbed wire), undoing when being stretched..."

And you can read the remainder of that.

And it's referenced in Item No. 27 using the Bates code.

A Sofradim document from 2004, touting a new polyester mesh product, stated, "Surgeons have used polypropylene mesh as a reinforcement device, but the material is known to shrink, contract, and stiffen. Because --"

Q I don't mean to interrupt you, Doctor, but I see where you're talking -- reading -- you're just reading the report on Page 13, correct?

A Yes, that's correct.

Q Other than from documents given to you by the Plaintiffs' attorneys, do you have any other evidence that Bard and/or Sofradim had reason to question the efficacy or safety of the Avaulta products prior to their launch

on the market?

A So you mean, in addition to the ones I've cited already, are there other documents --

Q No.

A -- to suggest there are questions of safety and efficacy?

Q That wasn't my question.

Do you have any evidence that Bard and -- or Sofradim employees were questioning the safety and efficacy of these products prior to their introduction other than from the documents that the Plaintiffs sent you to review?

A Prior to the Plaintiffs sending me the documents, I had access to none of the Bard or Sofradim documents.

Q So the sole basis -- I guess this is my question. The sole basis for your opinion in that regard is the documents provided to you by the Plaintiffs' attorneys?

A No, it isn't. It's using judgment acquired over a lifetime of treating patients who have various disorders and being somewhat objective about being concerned about the

introduction of any type of care into patient practice.

A procedure that involves placing a synthetic permanent material into a contaminated field raises legitimate concerns on the question of -- in this case should raise questions with the manufacturer, the marketer, and ultimately to the physician.

So, I don't have a document that says that.

Q Now, this section of your report cites the French HAS study from November of 2006, correct?

A Yes, it does.

Q Had you ever seen that study before it was provided to you by the Plaintiffs' attorneys?

A No, I had not.

Q Had you ever seen any reference to that prior to the Plaintiffs' attorneys providing that to you?

A No, I had not.

Q Do you have any evidence, Dr. Shull, that Bard was aware of that study or that publication?

A No, I don't.

Q Do you know what the purpose of that study or that publication was?

A I was not involved in its production or publication. In reading it, I would presume the purpose was to highlight concerns about the use of mesh so that the people who were producing, marketing, selling and using mesh would be aware there had been questions that had been raised.

Q Now, is that just an assumption on your part?

MR. GARRARD: Object to the form of the question. Is what just an assumption?

BY MR. NORTH:

Q The purpose of that -- I mean --

A No one who wrote the article -- no one who published the article has corresponded with me about the -- the intention.

Q Do you know what the French HAS, what its purpose is?

A No, I do not.

Q Do you know whether it's a government entity or a private entity?

A I do not.

Q Do you know whether its task or sort of purpose is to assess whether new technologies or devices utilized in patients in France would be -- will be reimbursable under the French National Healthcare Plan?

A I don't know the answer to that. And I don't know about the French National Healthcare Plan in general.

Q So while you cite the French study, you do not know the exact context of why that publication was published or whether Bard knew about it; is that correct?

A I cite that publication because it raises -- it provides information and raises legitimate questions be answered, not just by the French, but by anyone who's interested in safety and efficacy of a product.

So the questions that they have posed are not geographically limited to France.

Q But you weren't aware of that until given to you by the Plaintiffs' attorneys, correct?

A That's accurate. I was not aware of this publication. I was aware that the issues which are raised are in one sense common sense

issues.

MR. MOELLER: What page do you cite that, sir?

MR. NORTH: It's 8, Page 8.

THE WITNESS: Page 8.

MR. MOELLER: Page 8, okay, thank you.

THE WITNESS: Yes. It is numbered -- would you like me to give you the number?

MR. NORTH: No, we've got that.

MR. MOELLER: Thank you.

BY MR. NORTH:

Q Are you aware of studies in the literature in the 2004-2005 time frame that found good results with the use of transvaginal mesh kits?

A I am not aware of any studies in 2005. If you mean a scientific study, I'm aware of no scientific study of use of mesh kits in 2005 that provided information about their safety or efficacy.

Q What's an H-shaped mesh product?

A Do you mind telling me what you're referencing here? Is there some reference in my report?

Q I've just seen that phrase before, H-shaped mesh products. Does that have any significance to you?

A My assumption would be that it is a product that if you looked at it in certain directions, it would appear to be similar to the letter H. Which would mean that there's something in the center and there are two perpendicular sides to it. And the something in the center could be equal to or unequal to the two things on the side.

That's not a term I've used, I don't believe.

Q Based on your report, it appears that you intend to give testimony of opinions regarding certain properties of the mesh material used in the Avaulta product; is that correct?

A Can you tell me where I'm referencing that?

Q Well, do you intend to give opinions regarding the propensity, if any, of the Avaulta mesh to shrink, shrinkage of the mesh?

A If I'm asked and I believe what I've indicated here, if I'm asked, I will say that I

believe it's the responsibility of the manufacturer to know these qualities not only in the laboratory, but in the patient herself.

Do I intend to say that I know about the properties in the laboratory? I do not.

Q So you are unable to say from your own personal knowledge or experience whether the mesh used in any of the Avaulta products shrinks or does not shrink; is that correct?

MR. GARRARD: Object to the form of your question. That's not what he said.

BY MR. NORTH:

Q Well, regardless is my question. Answer -- you can answer that question.

A There are several ways to evaluate systems that are used in the body. One is called an in vitro test, one is an in vivo test.

In vitro implies in a lab setting. Some of the qualities of a product can be tested through certain textile parameters, for example, mechanical stress and strain, size, weave, microscopic appearance.

That product then is exposed to something else, the deployment of the product,

its reaction in the body, the body's healing process around it, that becomes an in vivo evaluation.

The in vitro qualities can be used to predict what may happen in vivo. However, the actual knowledge of what's going to happen can't be acquired until the proposed product that's been testing in a lab has in fact been implanted in someone, in someone is alive and able to report information which is valuable to be known and physical examination can be done to detect what particular qualities you hope to learn.

So the lab testing and the final performance in a patient would not be the same thing.

Q My question --

A So I'm telling you I am not purporting to be an expert in the lab. I am purporting to be an expert physician who has seen women who have had surgery and have had various outcomes from surgery.

Q But I'm focused right now on one aspect of the mesh.

A Right.

Q Can you give an opinion one way or the other as to whether Avaulta mesh, the mesh in any of the Avaulta products shrinks?

A Based on the records we received, it could shrink anywhere from 10 to 50 percent.

Q You're basing that on a document you read that was furnished to you by the Plaintiffs' attorneys, correct?

A That's accurate.

Q You've done no independent assessment of that?

A I have not tested any Avaulta product.

Q And you're not qualified to test Avaulta products to determine their rate of shrinkage, if any, are you?

A I would say my only qualification and testing of products in general, not specifically Avaulta, would be seeing women who have had mesh products implanted and examining them and learning about the characteristics of their exam after they've had a product implanted.

Q But you've never seen an Avaulta explant that you were able to specifically

identify shrinkage in, correct?

A I have not seen an Avaulta explant that I saw before it was implanted and observed it, made any measurements, and then measured it again after it had been explanted.

Q Now, as far as contracture of mesh goes, any opinions you offer on the contracture of mesh are not things you've personally observed, correct?

MR. GARRARD: Object to the form of your question.

A The things that I have said about the change in the configuration of the mesh is based on my observation of mesh products which have been removed, and my observation of products that I have seen either at scientific meetings where someone's marketed it or I've seen it in the package or I myself have used a mid-urethral sling, for example, and seen a product before it's implanted.

So I have knowledge of seeing what products look like before they're put in the body and I have knowledge of seeing products when they've been explanted.

BY MR. NORTH:

Q But you've never seen that specifically with regard to the mesh in an Avaulta product, have you?

A I have not specifically quantified an Avaulta product which has not been implanted and followed that particular patient or any other patient and taken an Avaulta product and made an assessment of it specifically.

Q And because you haven't done that, you can't say that you've ever seen a piece of mesh from an Avaulta product that has shrunk or contracted, correct?

MR. GARRARD: Object to the form of the question.

A I can say that I've seen a piece of Avaulta mesh or other mesh products that does not look the same as a product that is in the package or has been removed from the package but not implanted into anyone.

BY MR. NORTH:

Q And you would expect a product to look different once it had been implanted in the human body and removed, wouldn't you?

A There are lots of differences that could occur. There are some that are very

obvious about being blood stained, for example. Others are more concerning about the change in the configuration, the gross configuration, the softness, the ability to move it, hold it.

Q Well, here's what I'm trying to understand. You keep referring to Avaulta and other mesh products. I want to ask you this question specific to Avaulta.

A Uh-huh.

Q As you sit here today, can you identify any past time when you saw a change in Avaulta mesh after if had been explanted, a change from after the explant compared to pre-implant?

A Every explant that I have seen, every explant that I have removed, does not appear similar to any product I have seen prior to its implantation. None of them look the same.

Q But with regard to Avaulta products and only Avaulta products, do you have a recollection of how the Avaulta explants looked different from the pristine version of the mesh?

A Rigid, irregular surfaces with scar tissue around it.

Q What patient was that removed from, do you know?

MR. GARRARD: Doctor --

A If I knew that, I couldn't tell you.

MR. GARRARD: I was fixing to say don't violate HIPAA.

BY MR. NORTH:

Q On how many occasions did you see an Avaulta explant in that condition?

A I think when you asked me before about the number of patients I have operated to remove Avaulta, you asked if it would be 10 or less, and I said I think that would probably be right.

Q Have you ever done any studies regarding pore size in mesh and how it contributes to the scar formation or any other phenomena?

A I personally have not done any test. I have read about it, but I haven't done any of the tests myself.

Q Other than what you may have read in the documents provided by the Plaintiffs' attorneys in this case, have you read any other things in the past about pore sizes in

polypropylene mesh?

A Yes, frequently. Because the number of scientific meetings I attend, the subject matter of using materials in reconstructive surgery is addressed.

And in fact, I've given talks about it myself using the various classifications, the Amid, A-M-I-D, classification, the macroporous, microporous. I'm familiar with all of that.

However, I haven't personally done any of that testing.

Q Do you know how the pore size of the Avaulta mesh products differs, if it does, from the pore size of the transvaginal mesh kits that were on the market by the time Avaulta was introduced?

A I do not.

Q Have you done any comparative studies of the pore size on Avaulta products with the pore size on other products?

A I have not.

Q Do you know whether the pore size in the Avaulta mesh is larger or smaller than the pore size on the TVT sling you used by Johnson

& Johnson?

A I do not know that.

Q Have you ever measured the pore size on the Johnson & Johnson?

A I have not.

Q You offer some opinions critical of the pore size in the Bard mesh, the Avaulta mesh in your report?

A Could you give me the reference and then I'll be happy to read that.

If I look at Page 14, the beginning paragraph: Bard knew that re size is critical to the proper function of surgical mesh. Adequately sized pores allow ingrowth of tissue, fight bacteria, and prevent scarification. Bard documents show the company recognized the need to have large pores to avoid contraction and what is described as "scar plate formation."

Q But --

A I have that referenced.

Q Yes.

All of your information regarding the size of Bard's -- the pore size of Bard's Avaulta mesh comes from the documents provided

to you by the Plaintiffs' attorneys in this case; is that correct?

A That's accurate.

Q And, again, you've done no independent assessment of that?

A I did not document that, in fact, these documents came from Bard to Mr. Garrard and his associates. So I guess it's possible that someone else's documents were sent to him and labeled as Bard, but I'm presuming these were Bard documents in his possession which he gave to me.

Q What do you understand to be degradation in a polypropylene mesh product?

A Degradation means the product itself would begin to lose some of its integrity and doesn't have the same characteristics that it had initially.

Q Have you ever personally observed degradation in an Avaulta mesh product?

A This is a microscopic appearance, and the answer is I have not looked at the products microscopically.

Q So you can't say whether you've seen degradation in an Avaulta mesh product or not?

A I haven't seen it microscopically.

Q And therefore, because you haven't seen it microscopically, you can't say whether you've seen it at all, correct?

A I can say that I have not seen it microscopically. That is not the same as saying it doesn't happen. I'm telling you I have not seen it microscopically and it's a microscopic observation, not a gross observation.

Q Right.

And you can't see it unless you do look at it microscopically, correct?

A It would depend on the phase of degradation. So if -- if you waited a long enough time until the product itself changed gross physical characteristics, you would be able to see it. But not -- at an early stage you would not be able to see that with the naked eye.

Q Do you know why shrinkage occurs in polypropylene mesh?

A The most commonly accepted reason for that is when mesh is put in place, first of all, it may be deformed when it's deployed,

when the mesh arms are deployed.

So, if I give you an example of something being as wide as my little finger, for example, and it has a woven pattern, depending on the direction of pull, I may be able to change the physical characteristics of that product simply by pulling on it.

So some of the changes can occur when in this particular case the product is deployed into a patient.

I've observed that, for example, in using mid-urethral slings, that the configuration of the product may change once you have passed a trocar and removed the protective sleeve.

In the case of the remainder of changes with contraction or shrinkage, if the deployment doesn't cause any change in the surface area or the configuration, when the fibroblast grow into the interstices of the product and scar formation occurs, scars generally contract.

And when they contract, they will possibly pull on the fibers of the mesh and change the configuration to make the mesh

shorter, more rigid, and ostensibly change the pore size.

The pore size that is done before the product is deployed is a very static measurement. Once wound healing has occurred, that product has changed its configuration and possibly the pore size will change. It would be unlikely it will get larger. If it changes, it would normally be smaller.

Q Dr. Shull, you told us earlier you've never worked for a medical device company. Have you ever run your own company of any sort?

A I have a business with my daughter and son-in-law which is unrelated to medicine. And I haven't run that, but I have been the signator on the mortgage for the business.

Q The financier?

A That's not to be confused with running it.

Q What sort of business is that?

A I'm actually president of CIA, LLC. Culinary Institutes of America. Not the Central Intelligence Agency.

Q And what kind of business is that in?

A Restaurant.

Q How many -- well, do you have any active managerial role in that company?

A If they don't pay the mortgage, I do.

Q Other than financing, do you have any role there?

A No.

Q How many employees does that company have?

A That varies. Full-time employees, I'm guessing they have 10 to 15.

Q Is that company subject to FDA regulations?

A I don't think so.

Q Have you ever been involved in running any other company?

A No.

Q Have you ever had to make decisions on how to run a company in compliance with federal regulations?

A I've sat on the board of trustees of our hospital, so the truth is many of our responsibilities relate to compliance issues, for example, compliance with various agencies.

I don't remember specifically the Food & Drug Administration, but governmental

agencies, yes. All medical facilities are responsible to a variety of governmental agencies.

Q Have you ever served on the board of directors of a medical device company?

A No, I have not.

Q Have you ever served on the board of directors of any publicly held company?

A No, I have not.

Q Other than the board of trustees for your clinic, have you ever served on any board?

A No. I've served on the board for our clinic physician organization and for our hospital, so those two, but no other.

Q And you've never spoken to anyone at Bard as to why they decided -- or as to why they made the decisions they did with regard to clinical studies, correct?

A I haven't spoken to anyone about that.

Q And your sole basis for any knowledge regarding decisions made with regard to clinical studies comes from the documents provided to you by the Plaintiffs' attorneys?

MR. GARRARD: Wait a second.

Do you mean as to Bard?

BY MR. NORTH:

Q As to Bard.

A Do you mind asking me the question again?

Q The sole basis of your knowledge regarding Bard's decisions with regard to clinical studies and the Avaulta products comes from the documents provided to you by the Plaintiffs' attorneys and that limited number of Bard employee depositions provided to you; is that correct?

A That's correct.

Q And the same thing would be true as to the decision making that went into the drafting of the instructions for use with regard to the product; is that correct?

MR. GARRARD: I'm sorry. I wasn't --

A I don't believe I received any information --

MR. GARRARD: Wait, wait, wait, wait. Would you just ask that again because I didn't understand your question.

BY MR. NORTH:

Q The sole basis of your knowledge with

regard to Bard's decision making as to the instructions for use for the Avaulta products comes from the documents provided to you by the Plaintiffs' attorneys and the number of employee depositions they provided you?

A I do not believe there's anything in the documents I have received that goes into the decision making by Bard to create an information for use document.

I have read the document. I have not read the process which Bard used to produce the document.

Q A number of your opinions in your report seem to suggest the motivation or the intent of Bard employees in doing certain things. Would you agree with that?

MR. GARRARD: Object to the form of your question.

A My report suggests what I have read about Bard's interest in working with Sofradim, the predicate product which Sofradim had helped to develop, about the subsequent discussions about safety and efficacy of the products.

I read information from territorial managers, salespeople, and physicians who have

used the products.

Is that what you're asking me about?

BY MR. NORTH:

Q And a number of those opinions or statements you make in your report attributes certain intentions or motivations to Bard and/or its individual employees, would you agree with me that?

A Could you give me an example of that? I'd be happy to address the specific one if you could tell me what it is.

Q I'll tell you what, since we'll be coming back a second day, and so I don't bog this down, I will have that ready for the second day.

A Okay.

MR. GARRARD: Can I have a personal privilege for just one second?

MR. NORTH: What's that?

MR. GARRARD: Can I have a personal privilege for just one second?

MR. NORTH: Absolutely.

VIDEO TECHNICIAN: We're off the record. The time is 2:00.

(Recess taken.)

VIDEO TECHNICIAN: We are back on the record. The time is 2:02.

You may continue, sir.

BY MR. NORTH:

Q On Page 17 of your report, Doctor, you state that you have observed banding of the arms and bunching of the central mesh piece with these devices.

A I'm looking for that specific --

Q Yeah, I'm having a hard time finding it, too. I may have the wrong page here.

I'm sorry, there you say, I saw it, it was taut and rigid. Towards the bottom of the page, and let me quote this, you say: When the mesh deforms and becomes cord-like, rigid, and taut, it produces an instrument that can saw into the issue and become the source of the pain that I see frequently in these patients.

A Yes.

Q Have you ever seen a piece of Avaulta mesh that had become cord-like, rigid, and taut?

MR. GARRARD: He prefaced that with watching the video, Richard.

A Whenever I operate on someone and do

an explant surgery, the indications would usually be bleeding, exposed mesh, pain for the sexual -- the male sexual partner or a pain on the part of the woman who is having surgery.

In the case of the woman herself having pain and she's had a mesh kit application to the anterior or a posterior compartment, invariably one or more of the arms is tightly stretched across the anterior or posterior compartment, and the central portion may also be tightly stretched, and/or crumpled up as opposed to lying flat as it was originally deployed into the patient.

So that would be an expected finding to have one or more of those issues.

On the physical exam of a patient prior to surgery, one of the characteristics, which I believe was mentioned by the consulting physicians in these four women, and is seen in the patients I personally care for, and as described in the literature, that you can feel a band-like substance which is not normally felt in women who have not had these particular procedures performed.

BY MR. NORTH:

Q Have you ever personally seen that with an Avaulta product?

A On the Avaulta products that were removed, I would have seen one or more of these things. So the answer to that is yes. Do I know was it Avaulta -- Avaulta Solo or Avaulta Plus, I do not know that.

Q Doctor, you have not examined any explanted material from any of the Plaintiffs whose medical records you reviewed, have you?

A I have not seen any material, I have not examined any patient that is in the list, and I have not spoken to any of the patients, nor have I spoken to their consulting or primary care doctors.

Q And because of that, you do not know whether there was shrinkage in the Avaulta mesh in any of those Plaintiffs, do you?

MR. GARRARD: Object to the form of your question. He's already referenced that in terms of his review of the records.

MR. NORTH: Objection to the speaking objection.

A The records from the primary treating doctors and/or the consulting doctors suggest

they can see or feel the mesh products in these patients.

BY MR. NORTH:

Q That's not my question. My question has to do with shrinkage.

Are you able to say whether there was any shrinkage in the mesh implanted in the Plaintiffs whose records you reviewed?

MR. GARRARD: Same objection.

A Tell me how you would like me to define that I know it shrank. What parameters are you wanting me to use for that? Do you mean did I know that it was measured and it was shorter than it was before it was implanted?

BY MR. NORTH:

Q Well, Doctor, it's a given that you believe these people had complications related to the mesh.

A Right.

Q But I'm talking specifically about shrinkage. Do you have any knowledge -- can you point to -- do you have any personal knowledge that the mesh in any of those Plaintiffs whose records you reviewed actually experienced shrinkage?

MR. GARRARD: Do you mean independent of what he reviewed in the medical records?

BY MR. NORTH:

Q Do any of the medical records say the mesh shrunk?

A I'll have to go back and look at that to get that specific wording.

When I read the operative notes, when the primary procedure was performed, the doctors who performed them indicated that the products were left with the ability to pass an instrument between the product and the surrounding viscera, the bowel, the bladder, for example.

So the doctor specifically indicated they left a space and that the arms were deployed.

When the patients return for subsequent surgery and the preoperative evaluation, I believe every record indicated that the examining doctor could feel a tight band, a tender spot, something that reproduced the pain. And in one or more of the operative notes, it was documented that the mesh had itself had folded on itself.

Did someone use the term "shrinkage"? I would have to go back in the records and see if that specific word was used.

My assessment of the situation is that the product was left tension free and there now is tight banding tenderness. That something happened to change the configuration. Whether the product itself shrank or whether the product was contracted because of scar tissue is in one sense a question of definition.

The product itself was not the same configuration as it was when it was deployed.

Q Doctor, I'm -- with all due respect, I still don't think you've answered the question. I understand that these patients' records show complications that you associate with the implantation of the mesh; is that correct?

A That's accurate.

Q And you believe that in some of these instances the configuration of the mesh would have changed, correct?

A Based on my review of the records, I believe that is true.

Q But you can't specifically say that any configuration change was shrinkage in any of those mesh products, can you?

MR. GARRARD: Object to the form of the question. He's already answered that.

A If the term "shrinkage" means the product had different dimensions than it had before it was implanted, I do not have the pre-implantation measurements and I do not have the post implantation measurements.

BY MR. NORTH:

Q And so the same thing would be true about contracture; is that correct?

MR. GARRARD: Object to the form of your question. He's already answer you.

A The other part, there is no way to tell when a product has been implanted how much is removed.

So let's presume that I measured a product before its implantation and I knew its exact area based on a geometric formula. I now explant the product and calculate the area again based on a geometric formula.

If I knew the original area and the area at explantation, I could presume one of

two things, that I took a defined percentage of the product out. The fallacy of that thinking is it is practically impossible to remove the entire product.

So measuring what was removed doesn't tell you how much of the product was removed. In order to know that, you would have to know how much is remaining in the body. And there's not a good way to know that.

So whether you ask me if it's shrinking or contracting, that's almost -- it's a semantic differentiation. I think what I'm saying to you is the area of the product that is laid out in a flat surface has changed.

BY MR. NORTH:

Q Degradation. You can't say one way or the other whether any of the mesh implanted in the women whose records you reviewed underwent a degradation process, can you?

A I cannot.

Q Are you able to say whether any of the women whose records you reviewed had scar plate formation?

A I can only go by the records of the examining physicians to indicate there's

scarring in the area of the vaginal canal where they're operating.

In at least of the few operative notes, if not all, the term "scarring" is used. I don't know that the term "scar plate" is specifically used by either physician.

Q But the fact of the matter is, that whatever opinions you may have regarding the condition of the mesh or what happened to the mesh in those individual Plaintiffs is based on the medical records and doctors' depositions that you've reviewed; is that correct?

A Would you ask me that again, please? I missed the first part.

Q Your opinions as to what may have occurred with the mesh implanted in these women, whose records you reviewed, those opinions are based only on the medical records and the depositions, perhaps, of the treating physicians, correct?

A No, that isn't correct.

Q What else is it --

A My -- my conclusions are based on my professional experience, my professional education, my examination of women who have had

complications of surgery, my interviews with them, with their spouses, my examination of them, my operating on them, in addition to the information provided in these records.

So, otherwise, you would be presuming I'm making -- drawing a conclusion disassociated with anything else in my background of knowledge and experience, and that isn't true.

Q I guess my question is more this, Dr. Shull. You don't have, and I think you've conceded this, any personal knowledge about what happened to the mesh in these women because you never examined any pathology from them, and you've never examined them, and you've never taken -- or never talked to their treating physicians, would you agree with that?

A I have not seen them, examined them, talked to them, spoken to or consulted with their treating physicians.

The information I have about these women and their care comes from their medical records by the physicians who treated them in their communities.

Q Okay.

MR. NORTH: You know, it's close to 2:30 and I'm getting ready to start a whole new area. It may be a good point to stop.

Are you comfortable with that?

MR. MOELLER: Sure.

VIDEO TECHNICIAN: You want to go off the record?

MR. NORTH: Thank you so much.

MR. GARRARD: Can we agree that --

VIDEO TECHNICIAN: Do you want to go off the record?

MR. NORTH: Yeah.

VIDEO TECHNICIAN: Stand by, please.

MR. GARRARD: This doesn't have to be on the video, but I do want the court reporter.

Can we agree that we don't need to do any errata sheet until we conclude the next version?

MR. NORTH: Any what?

MR. GARRARD: Errata sheet until --

MR. NORTH: Oh, yes, absolutely.

And can we also agree on the record, I think, what Margaret and I agreed to off the record, that between now and the continuation of this deposition she will make and scan and

send to me copies of all your handwritten notes.

THE WITNESS: Uh-huh.

MR. NORTH: Send those to us.

And if there's anything else original here besides, you know, Bard documents or depositions or medical literature, that you'll send that to us. And then we'll have those ready to use at the next continuation.

MR. GARRARD: When you say original, I don't know what you mean.

MR. NORTH: I mean, handwritten notes. Something besides the documents you all have sent him or medical articles --

MR. GARRARD: Okay.

MR. NORTH: -- that he's collected.

MR. GARRARD: Sure.

MR. NORTH: In other words, something that's not on this jump drive or Exhibit B.

MS. THOMPSON: Uh-huh, yeah, for sure.

MR. NORTH: Okay.

MS. THOMPSON: And I believe that will be only these -- these handwritten notes.

MR. NORTH: Yeah, that's what I

think, and the billing reference we already have.

MS. THOMPSON: We'll confirm there is nothing else.

MR. NORTH: Sure.

MR. GARRARD: Okay.

(Signature reserved.)

(Deposition concluded at 2:20 p.m.)

C E R T I F I C A T E

STATE OF GEORGIA:

FULTON COUNTY:

I hereby certify that the foregoing transcript was taken down, as stated in the caption, and the colloquies, questions, and answers were reduced to typewriting under my direction; that the transcript is a true and correct record of the evidence given.

I further certify that I am not a relative or employee or attorney of any party, nor am I financially interested in the outcome of the action.

This 18th day of February, 2013.

_____

Judith L. Leitz Moran, CCR-B-2312

VIA EMAIL

Date: 2/18/2013

To: Henry Garrard

Re: Signature of Deponent Bobbie Shull, M.D.

Greetings:

The deponent has reserved the right to read and sign. Please have the deponent review the attached .pdf transcript, noting any changes or corrections on the attached .pdf Errata. The deponent may fill out the Errata electronically or print and fill out manually.

Once the Errata is signed by the deponent and notarized, please mail it to the offices of Tiffany Alley (below).

When the signed Errata is returned to us, we will seal and forward to the taking attorney to file with the original transcript. We will also send copies of the Errata to all ordering parties.

If the signed Errata is not returned within the time below, the original transcript may be filed with the court without the signature of the deponent.

Date Errata due back at our offices: 3/21/2013

Please send completed Errata to:
Tiffany Alley Reporting & Video
3348 Peachtree Rd NE, Tower 200, Ste 700
Atlanta, Georgia 30326
(770) 343-9696